ENGLISH

CRANEX® 3D

3D Dental Imaging System

User's Manual

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Copyright

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1 Introduction

1.1 CRANEX® 3D

SOREDEX CRANEX® 3D (hereafter called “the unit”) is a high quality dental imaging system designed to take images of the dento-maxillo-facial complies of the human skull. In order to take images with the unit you need a suitable PC hardware connected to the unit and SCANORA® software to manage images. The unit performs the following procedures:

Pan

- Adult panoramic
- Child panoramic (Reduced width and height)
- Bitewing
- TMJ, PA projection
- TMJ, lateral projection (axially corrected)
- Maxillary sinus

Ceph (optional)

- Cephalometric Full size Lateral
- Cephalometric Reduced size lateral
- Cephalometric posterior-anterior projection PA / AP
- Reverse Towne projection
- Waters view
- Carpus (Not in USA and Canada and Canada)

3D (optional)

- XS 61x41 mm Field of View
- Midi 61x78 mm Field of view

1.2 Intended use

The unit must only be used and operated by dentist and other qualified professionals. The unit must only be used to take panoramic, cephalometric and 3D images of the dento-maxillofacial complex of the human skull. It must not be used to take images of any other part of the human body.

Note that panoramic and 3D exposures should not be used if conventional intraoral radiographic images (bitewing exposures) would suffice.

Note that cone beam computerized tomography images are not adequate for the analysis of soft tissue.

USA only

CAUTION! *Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.*

1.3 About this manual

This manual describes how to set up and use the unit. Please read this user's manual before operating the unit for the first time.

CAUTION! *It is important to read the warnings and precautions, listed in section 1.6, before operating the unit for the first time. It is also important to observe these warnings and precautions whenever the unit is used.*

1.4 Abbreviations used in this manual

FOV = Field Of View. The cylindrical 3D volume that is reconstructed by the system.

ROI = Region Of Interest. The anatomical area or region of the patient that you are interested to examine.

ACS = Automatic Collimator Selector

AES = Automatic Exposure Setting

1.5 Associated documentation

The SCANORA® software user's manual or the user's manual for the dental imaging software you are using.

The user's instructions supplied with the 3D imaging software you are using.

1.6 Warnings and precautions

To be observed during use

- There should be free space around the unit for safe operation.

- The unit must only be used to take the dental x-ray exposures described in this manual. The unit must NOT be used to take any other x-ray exposures. It is not safe to use the unit to take an x-ray exposures, that it is not designed for.

- Only professionally qualified dental and/or medical personnel are allowed to operate the unit and carry out any diagnoses based on output from the unit.

- The personnel operating the device must be adequately trained in CBCT technology with respect to principles of operation and radiation protection.

- The unit may be dangerous to the user and the patient, if the safety regulations in this manual are ignored, if the unit is not used in the way described in this manual and/or if the user does not know how to use the unit.

- This unit complies with the EMC (Electromagnetic Compatibility) according to IEC 60601-1-2. Radio transmitting equipment, cellular phones etc. shall not be used in close proximity of the unit as they could influence the performance of the unit.

- Because the x-ray limitations and safety regulations change from time to time, it is the responsibility of the user to make sure that all the valid safety regulations are fulfilled.

- In all examinations the user of the x-ray equipment should wear protective clothing. The operator does not need to be close to the patient during normal use. The protection against stray radiation can also be achieved by using the hand switch not less than 2 m (7 ft) from the focal spot and the xray beam.
  Operator should maintain visible contact with the patient and Technical factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.

- It is the responsibility of the doctor to decide if the x-ray exposure is necessary.

- The minimum height of patient that can be imaged is 120 cm (3.9 ft / 47.2) and the maximum is 200 cm (6ft / 78in). These heights only apply to patients with normal anatomy.

- When taking an x-ray exposure of a patient with exceptional anatomy (typically very tall or large) use the test mode (no x-rays) first to make sure that patient can be positioned correctly to the unit.

- Always use the lowest suitable x-ray dose to obtain the desired level of image quality.

- Avoid taking x-ray exposures of pregnant women.

- When taking an x-ray exposure of a child always use the lowest possible x-ray dose, the smallest possible image area and the lowest possible resolution that allows you to perform the required diagnostic task.

- If the patient is using a pacemaker, consult the manufacturer of the pacemaker before taking an exposure to confirm that the x-ray unit will not interfere with the operation of the pacemaker.

- Always use available disposable protective covers with the patient positioning accessories:

  Bite block cover
  Chin rest cover
  Ear holder cover

- Disinfect all the surfaces that the patient is in contact with after every patient.

- Panoramic and 3D should not be used for routine or screening examinations in which a radiograph is taken regardless of the presence or absence of clinical signs and symptoms. 3D imaging examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.

- Where it is likely that evaluation of soft tissues will be required as part of the patient’s radiological assessment, the imaging should be done using conventional medical CT or MR, rather than 3D imaging using Cone Beam technology.

General warnings

- There should be enough space around the installation place of the unit.
- The place where the unit is to be installed and the position from where the user will take exposures must be correctly shielded from the radiation that is generated when the unit is operated.
- The unit or its parts must not be changed or modified in any way without approval and instructions from SOREDEX.
- When servicing use only approved replacement parts supplied by SOREDEX.
- The Ethernet cable shall be unshielded CAT6, so that multiple chassis are not connected.
- If this device is used with 3rd party imaging application software not supplied by SOREDEX, the 3rd party imaging application software must comply with all local laws on patient information software. This includes the Medical Device Directive 93/42/EEC and/or relevant legal requirements in the USA.
- Do not connect any equipment to the unit that has not been supplied with the unit or that is not recommended by SOREDEX.
  The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.
- The aperture plate and tubehead housing are made of lead (Pb), which is a toxic material. Do not touch these parts with your bare hands.
- The unit must be installed according to the unit installation & Adjustments manual by a qualified technician.
- This product itself complies IEC 60601-1 medical safety standard but in order to the system incorporating also a PC to comply the standard, EITHER the PC has to be a medical PC OR the PC has to be located over 1,5 meters apart from the unit. The installer and the user of the system shall confirm that at least one of the above requirements is fulfilled. A PC is a medical one if it complies IEC 60601-1 standard and that is indicated in the accompanying documents of the PC.

- All service operations are performed by SOREDEX authorized service personnel.

1.7 Manufacturer's liability

As a manufacturer we can only assume liability of safe and reliable operation of this unit when

- The unit installation was performed according to the unit Installation & Adjustments Manual by qualified CRANEX® dealer and
- The unit is used according to the unit User Manual
- SCANORA® PC software was installed according to the Installation Manual for SCANORA® software.
- SCANORA® software is used according to User Manual for SCANORA® software.
- Maintenance and repairs are performed by a qualified CRANEX® Dealer
- Original or authorized spare parts are used

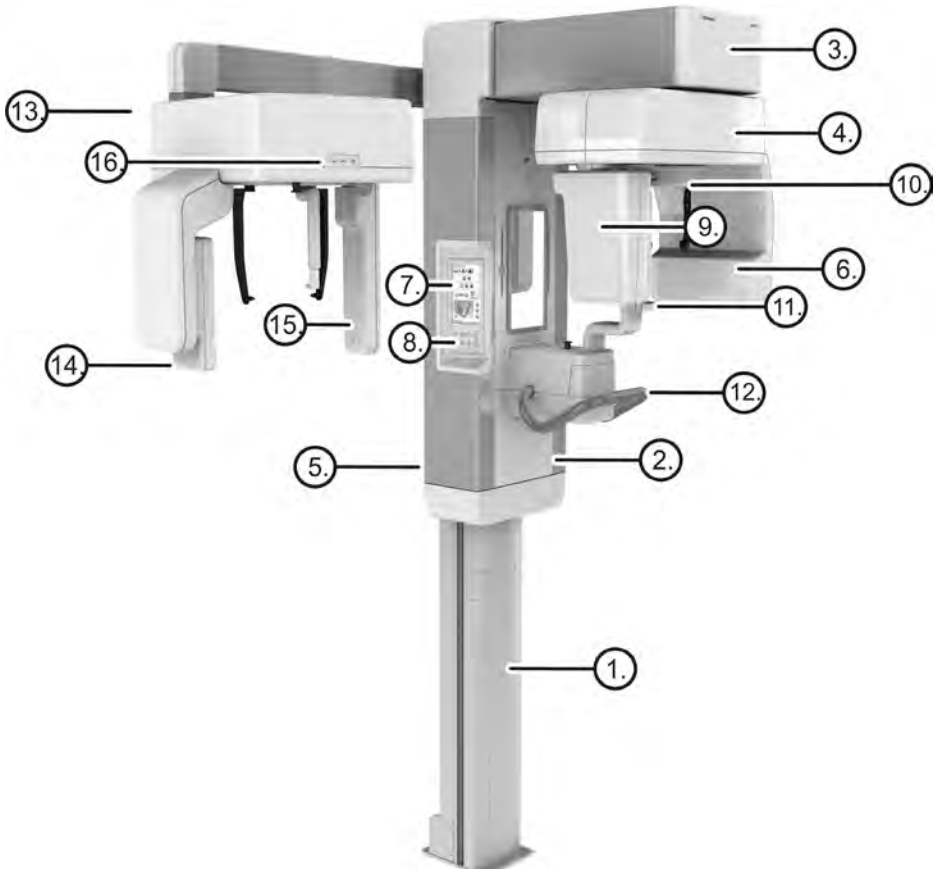
In order to guarantee maximal image quality for the entire life time of this high performance imaging system, we suggest that a special image quality assurance procedure (* and test object designed for image quality assurance purposes is used. Also we recommend that a qualified serviceman to check the unit to be in its original condition regarding electrical, radiation and mechanical safety according to our maintenance program described in more details in maintenance manual every year or after 2000 images. For more information please contact your local dealer.

*) According to EN61223-3-4 and DIN 6868-151

If service on the unit is performed, a work order describing the type and extent of repair must be provided by the service technician. This must contain information of changes of nominal data or work range performed. The work order must furthermore indicate the date of repair, the name of the company concerned and a valid signature. User should keep this work order for future references.

2 Unit description

2.1 Main parts and controls

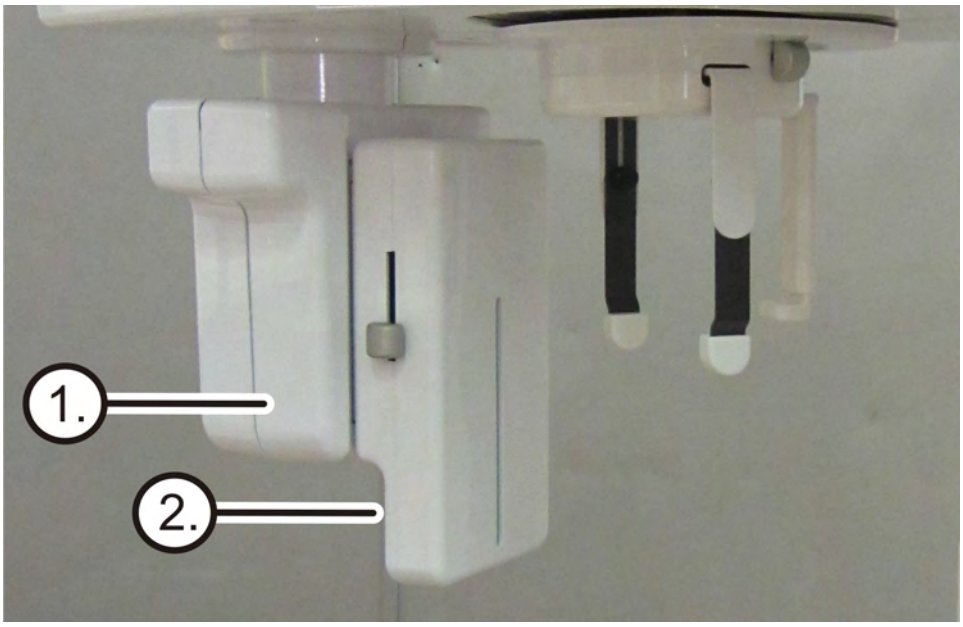


1. Column
2. Carriage
3. Main support
4. Rotating unit
5. On / off switch (rear of column) and main fuses
6. Tubehead assembly
7. ClearTouch™ control panel
8. Positioning panel
9. Sensor head
10. Head support
11. Chin rest
12. Handles
13. Cephalometric unit
14. Cephalometric sensor
15. Secondary collimator
16. Positioning panel

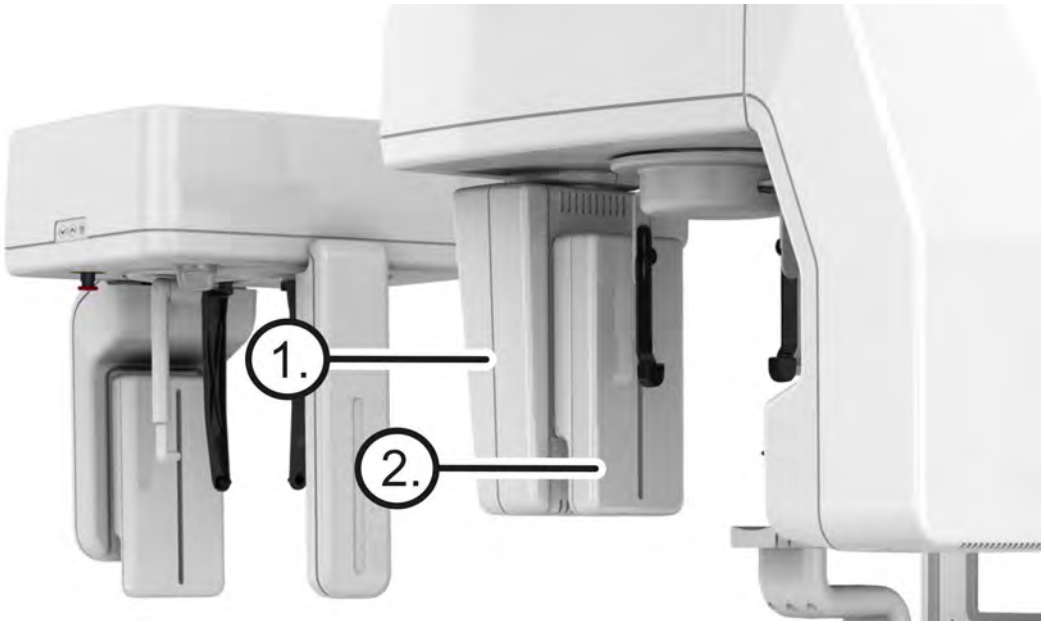
Fig 2.1. On / off switch and main fuses

PC with MDD approved dental imaging software and 3D viewing software.

All software must conform to the MDD and the relevant legal requirements in the USA.

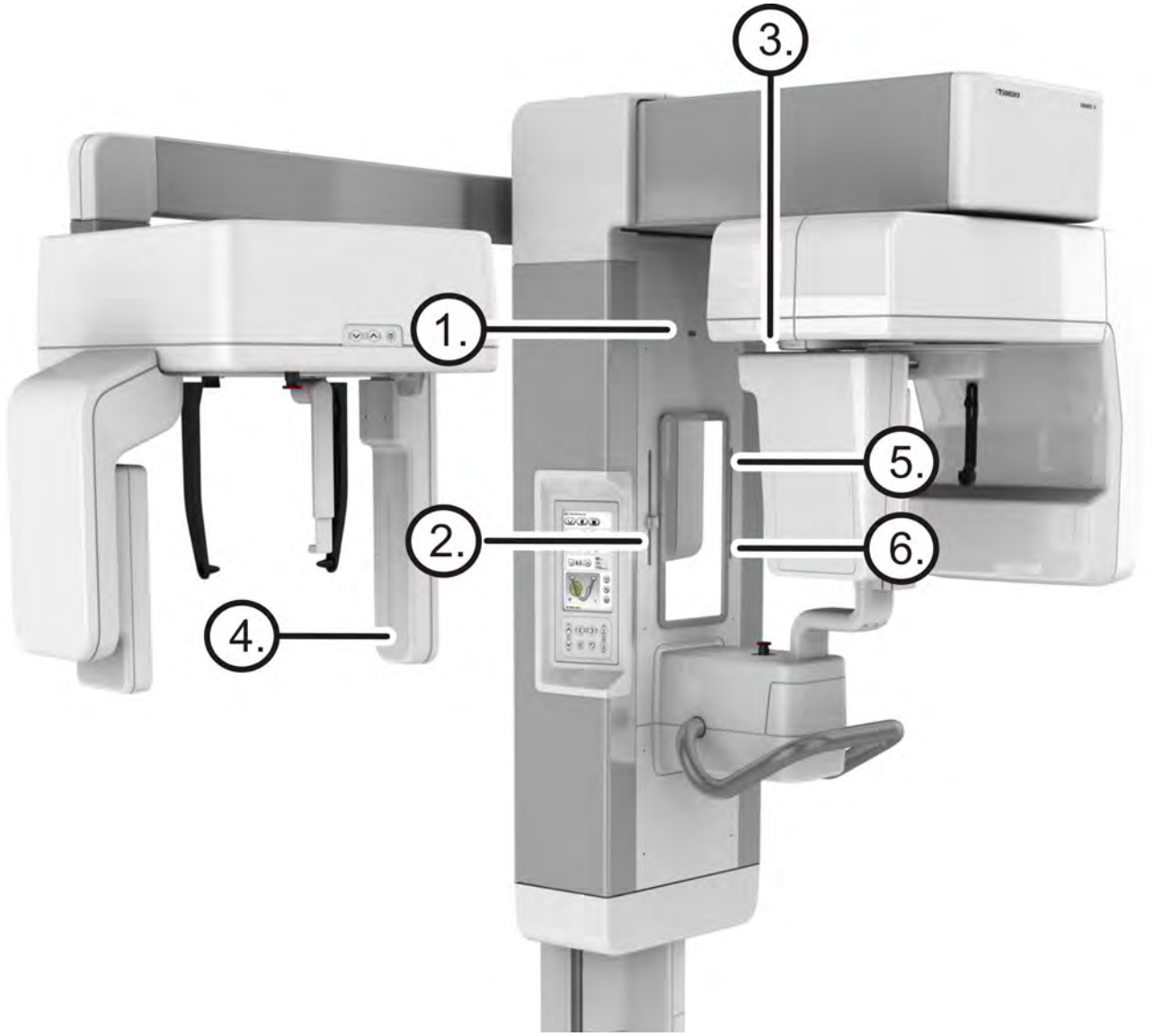


1. Sensor holder (PAN units only)
2. Panoramic sensor



1. 3D sensor (units with 3D option)
2. Panoramic sensor

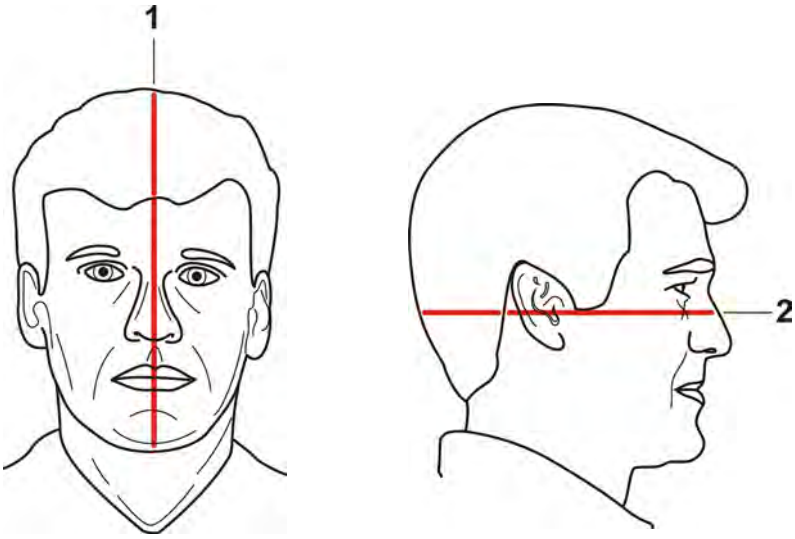
2.2 Patient positioning lights



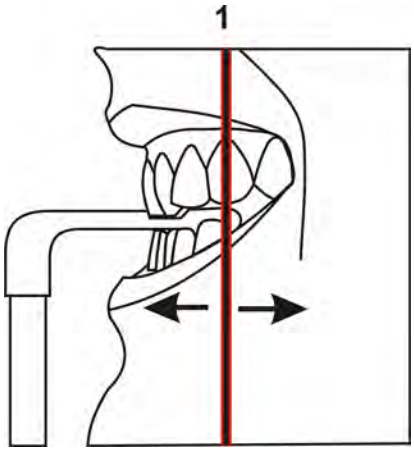
‘

1. Midsagittal
2. Frankfort-horizontal
3. Focal trough
4. Cephalometric Frankfort horizontal
5. Horizontal, top of FOV (3D option only)
6. Horizontal, bottom of FOV (3D option only)

Panoramic lights

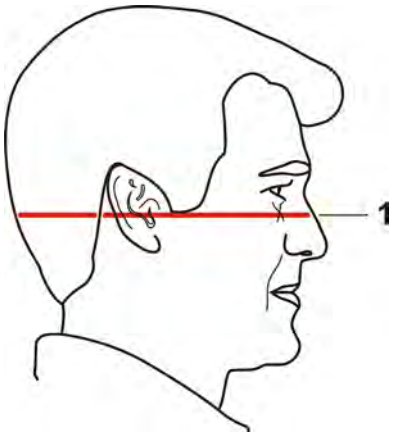


1. Midsagittal light
2. Frankfort-horizontal plane



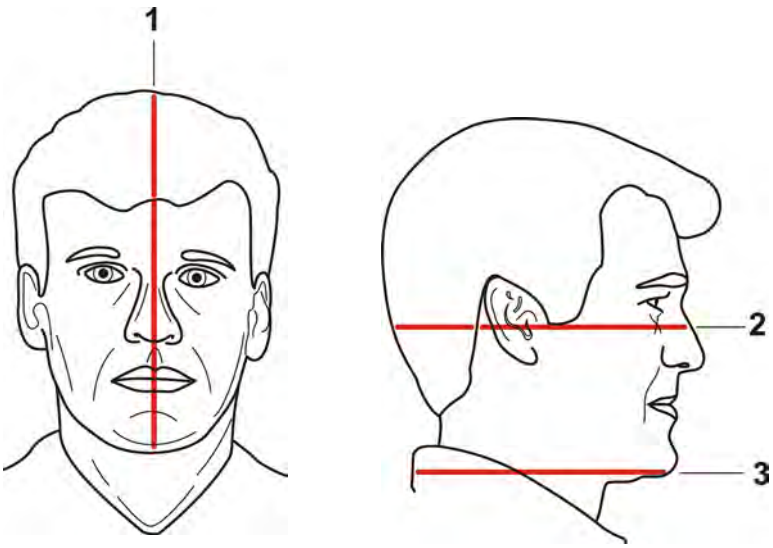
1. Focal trough light

Cephalometric lights



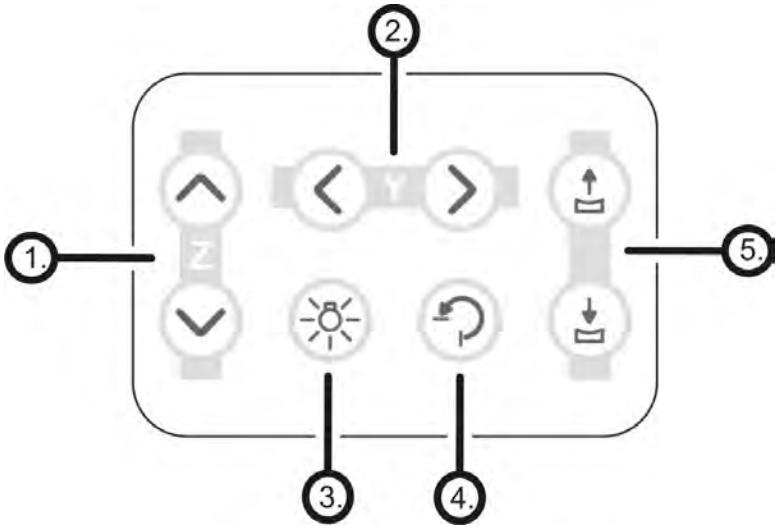
1. Frankfort-horizontal plane

3 D lights



1. Midsagittal light
2. Horizontal light, top of FOV
3. Horizontal light, bottom of FOV

2.3 Patient positioning panel

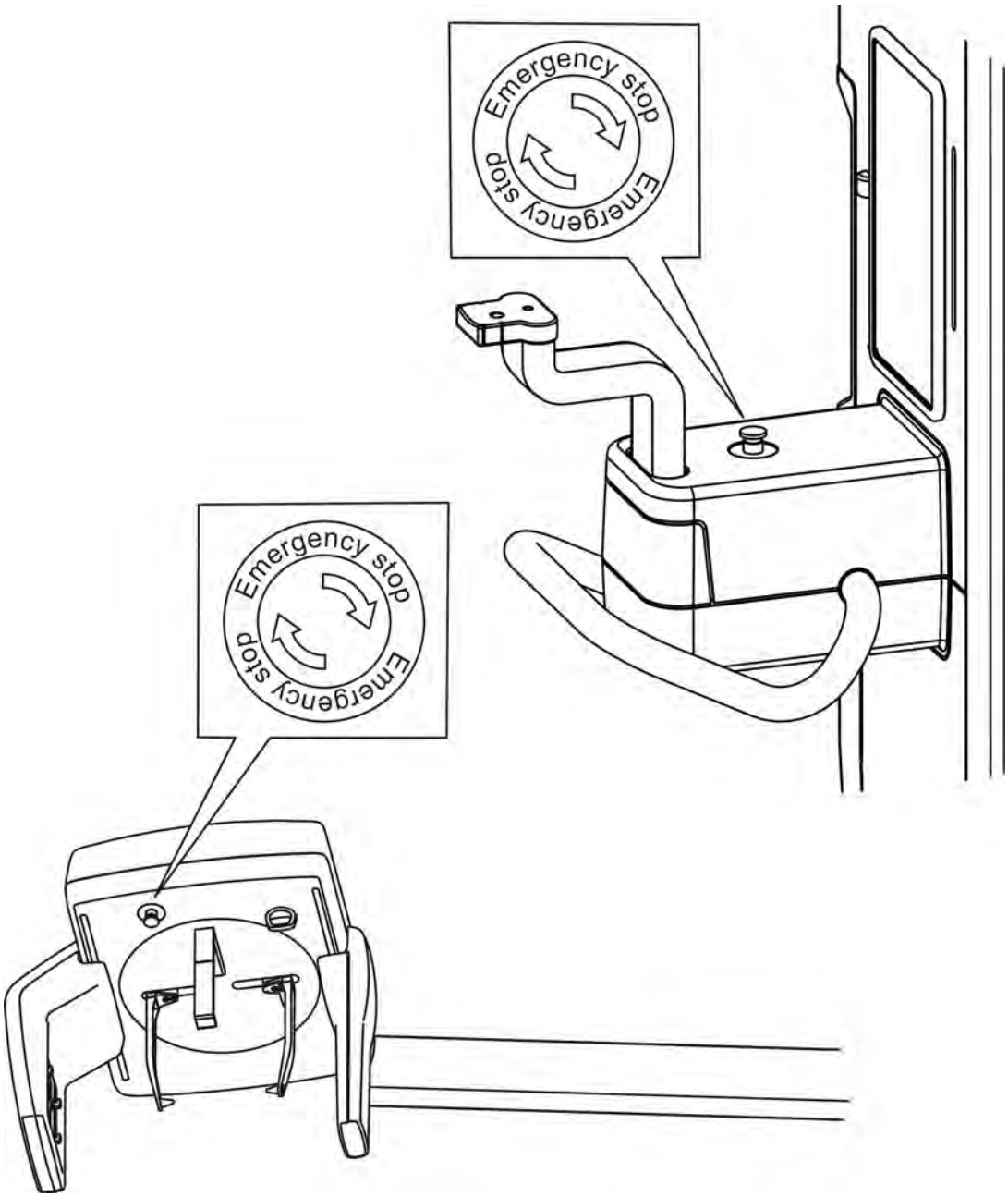


1. Carriage UP / DOWN (Z-movement)
2. Focal trough adjustment (Y-movement)
3. Positioning lasers ON/OFF
4. Return
5. Chin support UP / DOWN

2.4 Emergency stop switch

In case of malfunction of the exposure button or other protective devices of the unit, an emergency stop switch is provided near the handles and on the roof of the cephalostat head so that the patient can reach it.

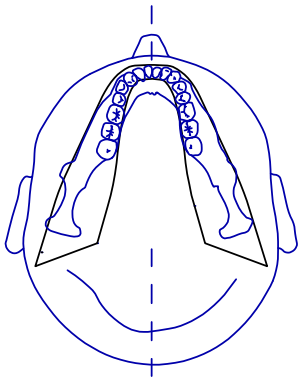
If the emergency stop switch is pressed during an exposure, the exposure is terminated immediately and the x-ray unit is completely stopped. An interrupted exposure cannot be continued later, but has to be retaken from the beginning.



Press to stop the unit, rotate to release.

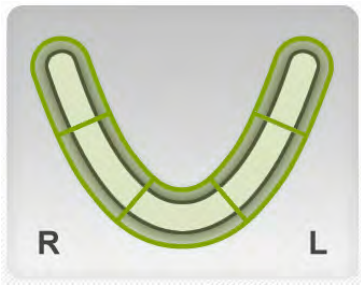
2.5 Imaging programs

2.5.1 Panoramic programs



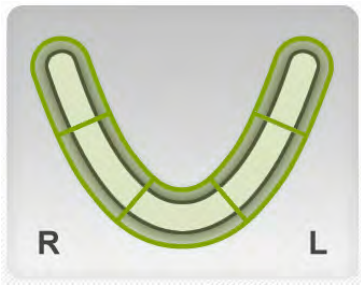
Adult: Magnification 1.3

Panoramic imaging provides general view of dental and facial anatomy based on panoramic imaging technic.

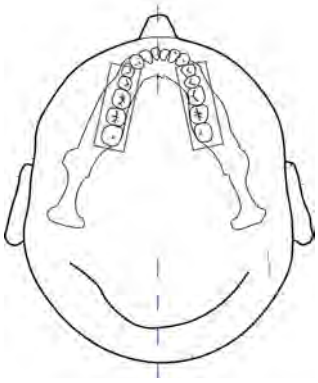


Adult panoramic 20,5 cm width x 11 cm height.

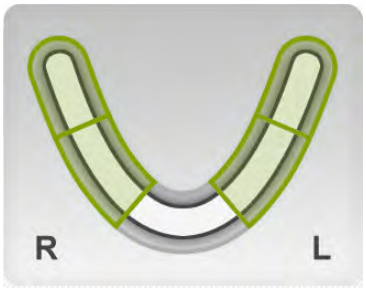
Child: Magnification 1.3



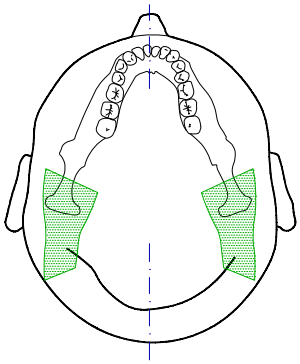
Child panoramic 11,5 cm width x 8,5 height**.**
Child panoramic has reduced width and height. Children can be imaged with less radiation dosage and shorter exposure time. Patients with jaw more narrow than average jaw can be exposed with this too.



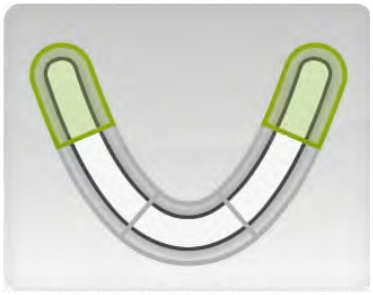
Bitewing: Magnification 1.3

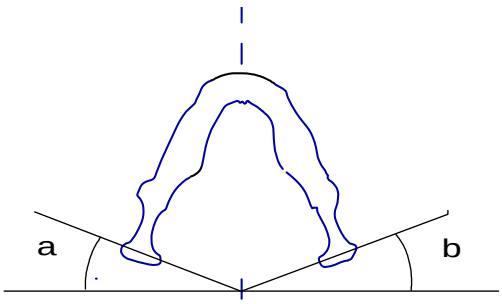


An orthogonal view of the dentition from the canine and posterior.

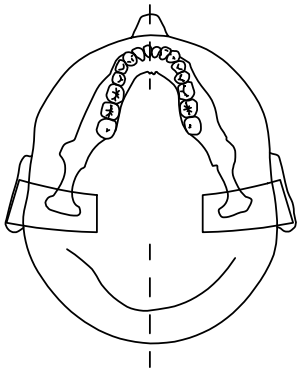


Lateral TMJ: Magnification 1.23



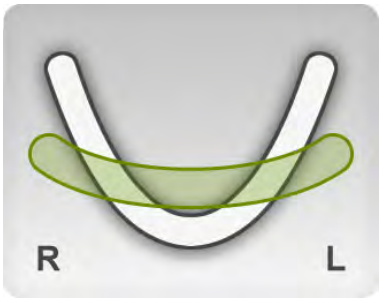


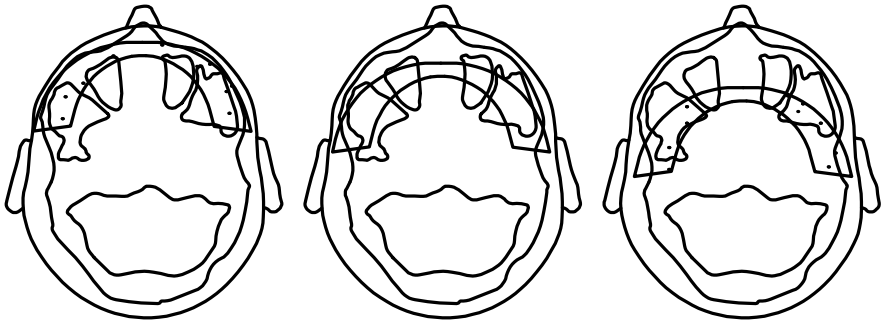
Lateral TMJ program provides a wide layer axially corrected views for the patient's left and right temporomandibular joints.



PA TMJ: Magnification 1.55

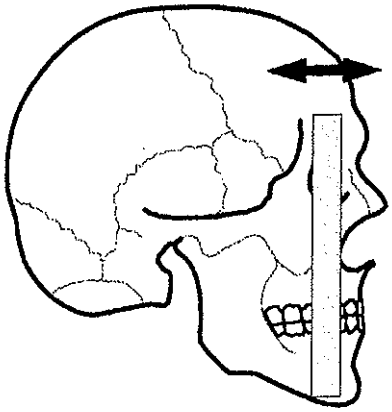
Maxillary Sinus: Magnification 1.3





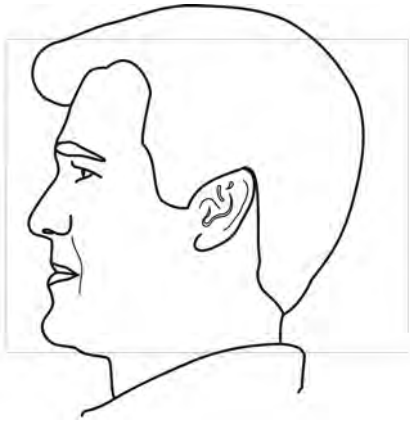
Mesial 10 mm | Start | Distal 10 mm

Maxillary Sinus program produces a pan - tomographic layer through the posterior maxillary sinus. The layer is flatter than the standard panoramic programs and is moved 18 mm backward. These images are helpful in visualizing the mid and posterior maxillary sinus.



2.5.2 Cephalometric programs

Cephalometric programs provide central projection images of patient skull and dental anatomy. Images are utilized in ortodontics and general diagnostics.



Full size lateral: Magnification 1.15

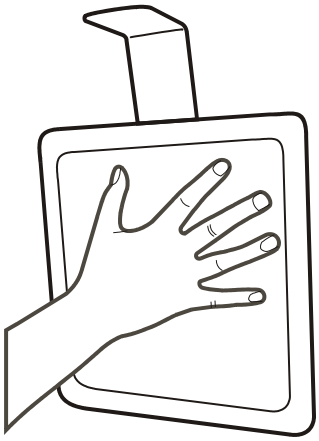
Field size: 22 x 26 cm (height x wide). Lateral Cephalostat uses a full height image field.

Reduced size lateral

Field size: 22 x 18 cm (height x wide). Reduced Width Lateral program has an optimized image width that is used e.g. for pediatric patients but also adult patients to reduce the radiation dose.

Cephalometric posterior-anterior (PA): Magnification 1.15

PA 22 x 20 cm (height x wide)



Carpus view (Not in USA and Canada and Canada)

2.5.3 3D programs

Cone beam 3D imaging enables seeing dentomaxillofacial anatomy of selected Field of View, FOV, helping with diagnostics and treatment planning. With 3D viewing software, user is able to analyze FOV area from multiple directions and see cross-sectional images from the area of interest.

XS FOV 61 x 41 mm (height x diameter)

High resolution

Standard resolution

Midi size FOV 61 x 78 mm (OPTIONAL)

Standard resolution or High resolution.

High resolution

Standard resolution

2.5.4 Exposure settings for 3D imaging

Exposure settings for 3D imaging							
NOTE! *Voltage settings is always 90kV with unit 3D modality.*							
Resolution	**FOV (h x w)**	**Exposure time**	**Scanning time**	**Amount of projections**	**mA** Low dose (DAP mGycm2)	**mA** High-quality (DAP mGycm2)	**mA** High-quality (DAP mGycm2)
High Res	61 x 41 mm	6,1 s	10 s	608	6.3 mA (298)	8 mA (379)	13 mA (593)
Std Res	61 x 41 mm	2,3 s	10 s	230	8 mA (145)	10 mA (181)	13 mA (227)
High Res	61 x 78 mm	12,6 s	20 s	1260	5 mA (491)	6.3 mA (619)	10 mA (983)
Std Res	61 x 78 mm	4,9 s	20 s	460	8 mA (302)	10 mA (372)	13 mA (472)

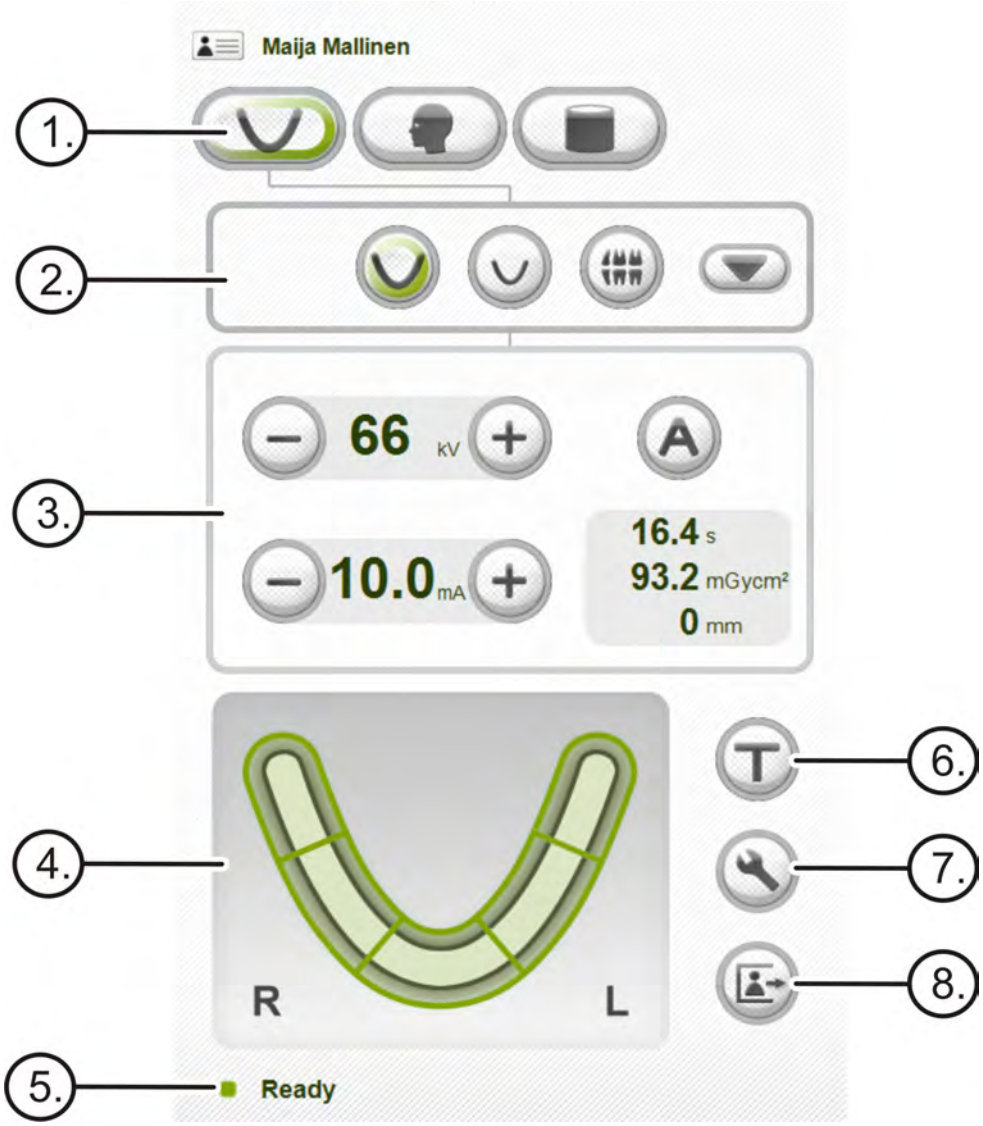
DAP values vary from unit to unit in relation to the x-ray tube output. Thus above values indicate average DAP values. In addition to these recommended values, there is a possibility to use the whole mA range if the user prefers.

Available mA ranges for each field of view sizes and resolution settings							
Resolution	**FOV (h x w)**	4 mA (DAP)	5 mA	6.3 mA	8 mA	10 mA	13 mA
High Res	61 x 41 mm	x	x	x	x	x	x
Std Res	61 x 41 mm			x	x	x	x
High Res	61 x 78 mm	x	x	x	x	x	
Std Res	61 x 78 mm			x	x	x	x

Exposure settings for scout imaging (default values)				
Resolution	**FOV (h x w)**	kV	mA	Scanning time
Scout	61 x 41 mm	90	13	0,02 s
Scout	61 x 78 mm	90	13	0,04 s

3 Controlling the unit

3.1 ClearTouch™ control panel



1. Modality selection
2. Program selection
3. Imaging values
4. Imaging area
5. Status of the unit
6. Test mode
7. Settings
8. Case end

3.2 Modality section

Select the modality button PAN, CEPH or 3D.

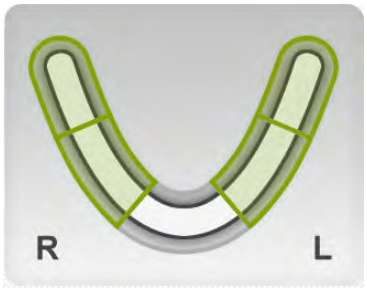
When panoramic modality is selected, a program specific dental arch is shown. This can be used for partial panoramic imaging.

Cephalometric programs have their own, program specific image figures and setting buttons for the start position of lateral scanning.

3D programs (two FOV sizes) have buttons for selecting low resolution, High resolution or scout image mode. The FOV for 3D imaging can be positioned on the XY-plane by selecting the center point of the FOV on the dental arch of the ClearTouch control panel. The FOV is positioned in the Z-direction by using the chin rest movement and positioning lights.

3.3 Sectional imaging

Dental arch on the touch panel shows the enabled and disabled arch sections from the result point of view. Select the image area from the dental arch.



3.4 Automatic Exposure setting (AES)

AES automatically recommends the exposure values according to the size of the patient's head in panoramic and cephalometric imaging. The AES is activated with active A button and by pushing Return button once. The AES suggest exposure values based on patient size. The user can change the value before exposure if needed by pushing **A** button again and changing the values.

3.4.1 AES values for Panoramic imaging

NOTE! *Values can be re-scaled by SOREDEX authorized service personnel.*

Adult, child panoramic, Bitewing, Sinus		
Head width (min)	**kV**	**mA**
19,3 cm (Max)	70	13
15,9 cm	70	10
14,2 cm	70	8
13,35 cm	66	8
12,925 cm	66	6,3
12,5 cm (Min)	66	5

AES values for TMJ Lat/PA		
Head width (min)	**kV**	**mA**
19,3 cm (Max)	73	16
15,9 cm	73	13
14,2 cm	73	10
13,35 cm	73	8
12,925 cm	73	6,3
12,5 cm (Min)	73	5

3.4.2 AES values for Cephalometric imaging

Lat/PA 100 V			
Head width (min)	**kV**	**mA**	**s**
17,3 cm (Max)	90	8	20
14,45 cm	90	8	20
12,65 cm	90	8	16
11,45 cm	90	8	12,5
10,55 cm	90	8	10
6,5 cm (Min)	85	8	10

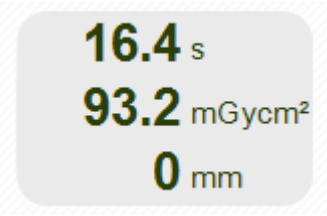
Ceph Lat/PA 120 V			
Head width (min)	**kV**	**mA**	**s**
17,3 cm (Max)	90	10	20
14,45 cm	90	10	20
12,65 cm	90	10	16
11,45 cm	90	10	12,5
10,55 cm	90	10	10
6,5 cm (Min)	85	8	10

Ceph Lat/PA 240 V			
Head width (min)	**kV**	**mA**	**s**
17,3 cm (Max)	90	12,6	16
14,45 cm	85	12,6	16
12,65 cm	85	12,6	12,5
11,45 cm	85	12,6	10
10,55 cm	85	10	10
6,5 cm (Min)	85	8	10

3.4.3 Exposure indicators and settings

kV value

mA value



Exposure time (s)

Dose value (mGycm^2)

Focal through light (mm)

Focal through light
y-layer position

Test mode

Automatic Exposure setting
(AES)

3.5 Status section

Status field shows when the unit is ready for capturing or any trouble occurs. Green and yellow colour indicate the status in question.

Ready for imaging

3.6 Other sections

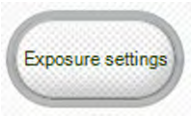
General settings
- User programs

Info

Languages

Quality assurance

Retrieve last image



Exposure settings

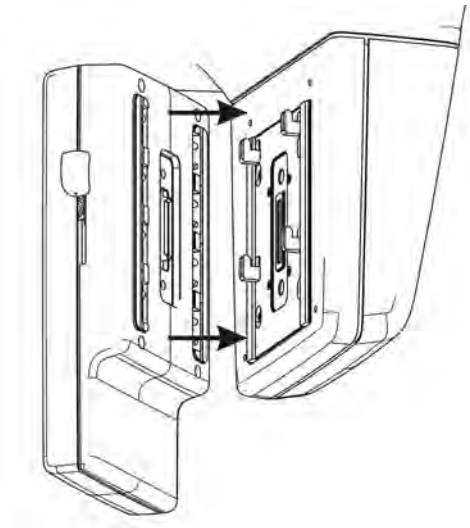
4 Using the unit

4.1 Attaching and removing the sensor

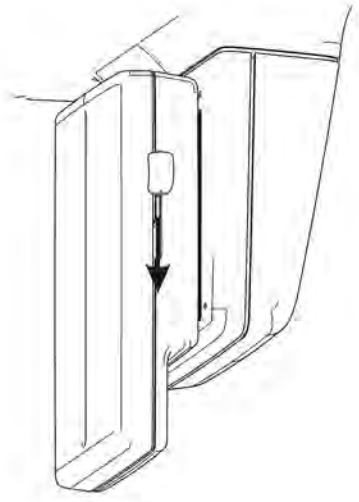
WARNING!
Handle the sensor with care as instructed in this manual. The sensor must not be dropped or exposed to impacts. A shock indicator inside the sensor shows if the sensor has been exposed to excess impact.

4.1.1 Attaching the sensor

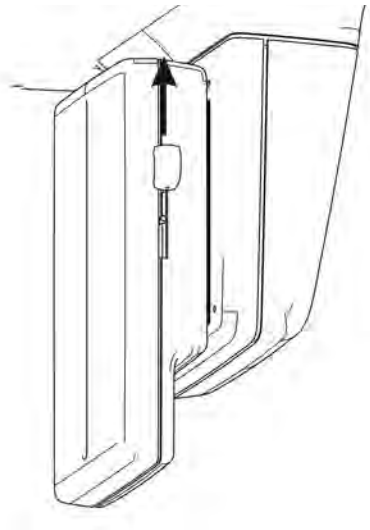
1. Insert the four slots on the rear of the sensor, into the four hooks in the sensor holder.



2. Slide the sensor downwards until it stops and then slide the locking knob down on the side of the sensor to lock the sensor in position.



4.1.2 Removing the sensor



1. Slide the locking knob upwards on the side of the sensor to unlock the sensor.
2. Slide the sensor up and remove it.

4.2 Preparing the system

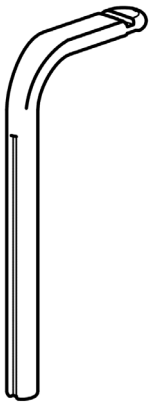
1. Switch on the unit and the PC.
2. **PC:** Start SCANORA® software (or 3rd party application).
3. **PC:** Open a new or existing patient or select a patient from the worklist. See the user's guide supplied with the dental imaging program.

4.3 Panoramic exposures

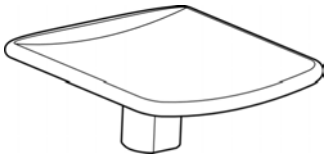
- Adult panoramic
- Child panoramic (Reduced width and height)
- Bitewing
- Maxillary sinus
- TMJ, PA/AP projection
- TMJ, lateral projection (axially corrected)

4.3.1 Positioning devices

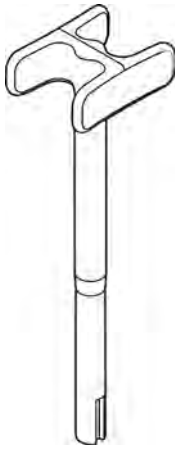
Bite block



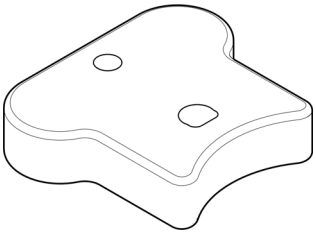
Chin plane



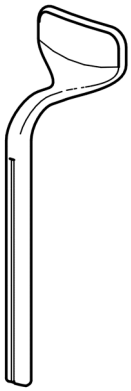
TMJ support



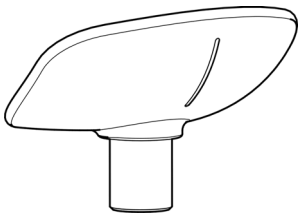
Chin rest holder



Lip holder for edentulous patients

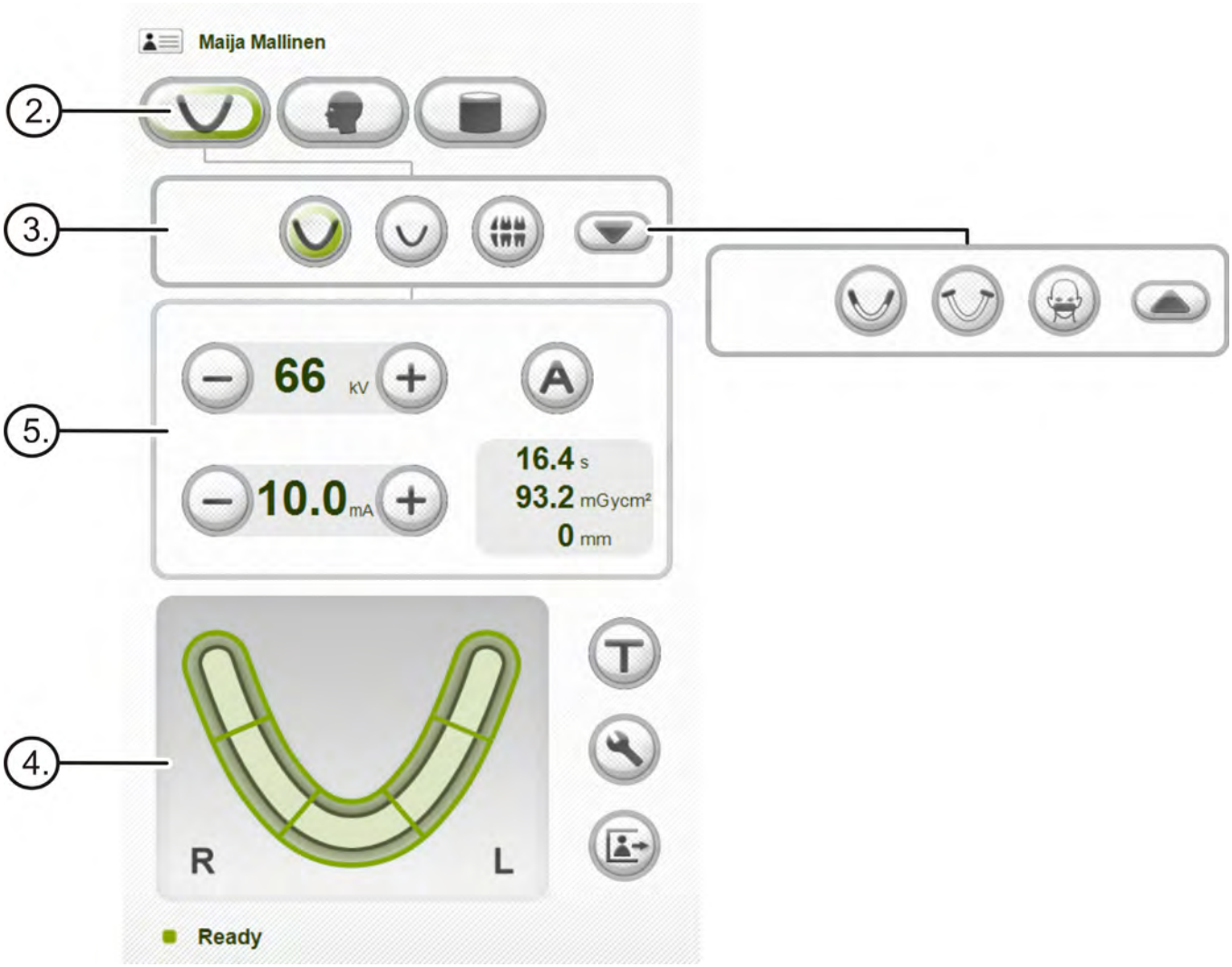


Chin cup



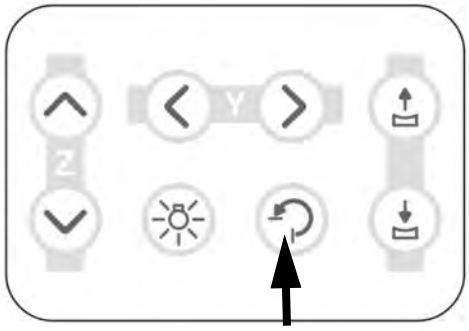
4.3.2 General instructions

1. **PC**: Click **Image Capture**.



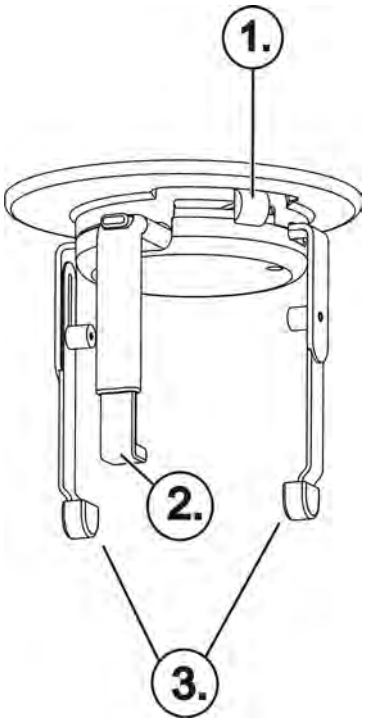
2. Select panoramic imaging.
3. Select the imaging program.
4. Any section of the dental arc can be selected for the sectional imaging to limit exposure area and reduce the radiation dosage.

5. Press the Return button to rotate the unit to ‘patient in’ position.



6. Open the temple supports.

   1 Temple support knob
   2 Forehead support
   3 Temple supports



7. Ask the patient to remove any spectacles, hearing aids, removable dentures, jewellery and hair clips and pins. Place a protective lead apron on the patient.

4.3.3 Patient positioning

4.3.3.1 Panoramic exposure

1. Insert the chin rest and bite rod with the bite block. Place the disposable covers.

NOTE! *Use a new disposable cover for every patient.*

2. Adjust the unit height.

3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Exposure can be taken also in sitting position. Ask the patient to take grip on the handles and bite on the bite block. Use the lipholder or the chin support for an edentulous patient.

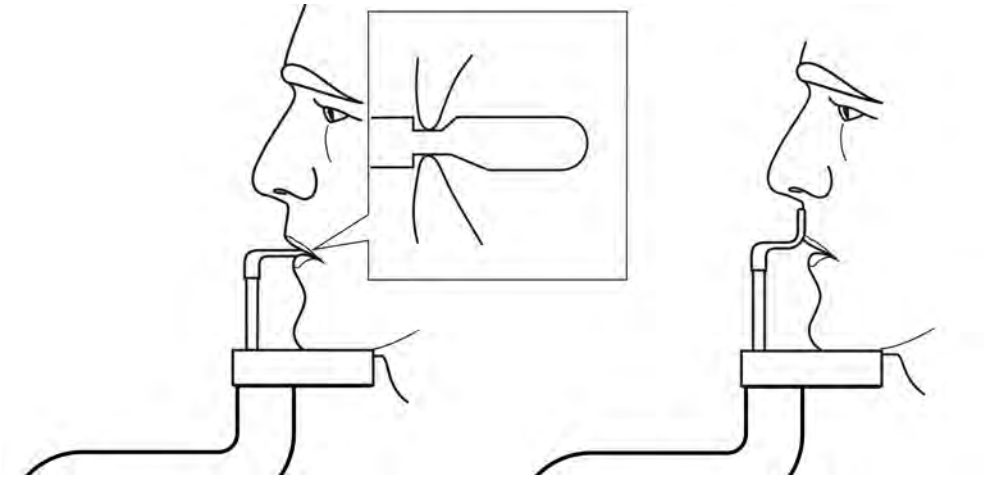
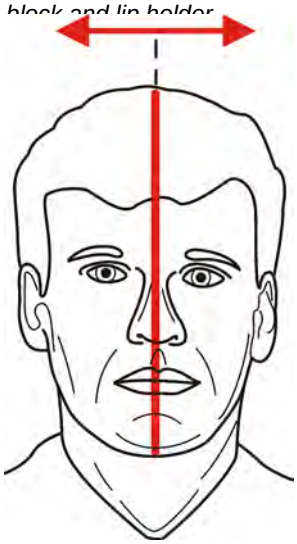


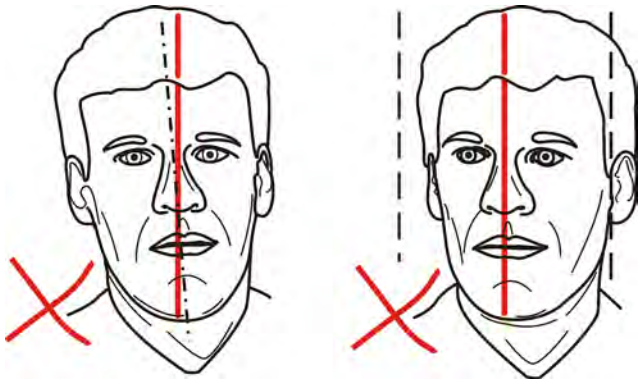
Fig 4.1. bite block and lip holder



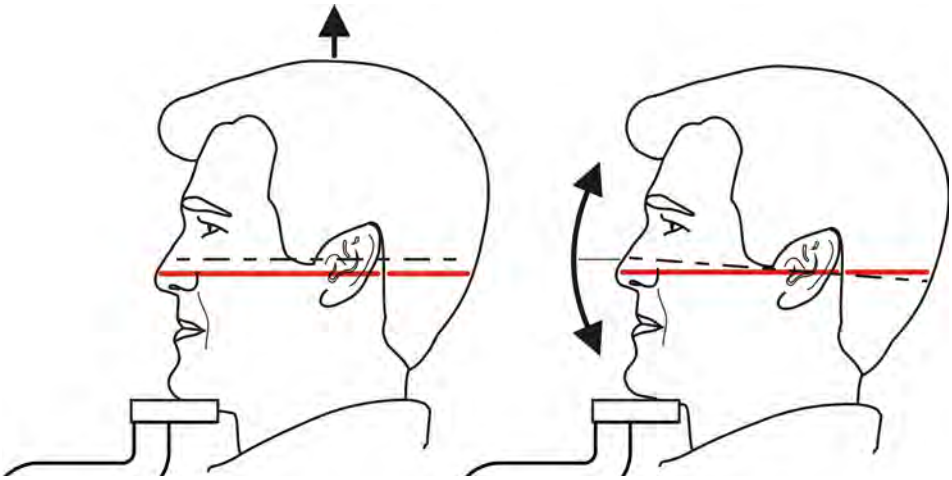
4. Ask the patient to take one step forward to straighten the spinal column. Patient is slightly leaning backwards during the imaging.

5. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.

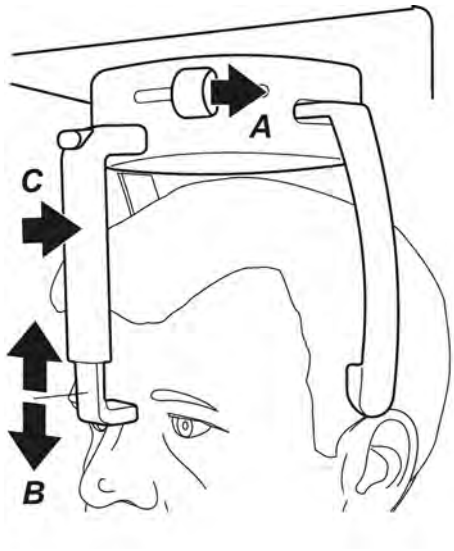
Make sure the patient’s head is not turned or tilted.



6. Adjust the height of the Frankfort-Horizontal plane (FH) laser to get the laser light over the orbita porion. Straighten the patient's head if needed.

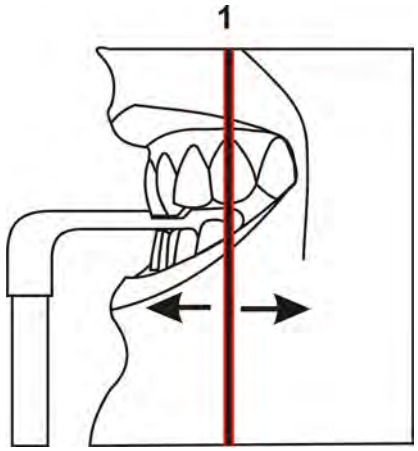


7. Close the temple supports by sliding the temple support knob to the right (A). Adjust the position of the nasion support (B) and push the forehead support in until it touches the patient's nasion (C).

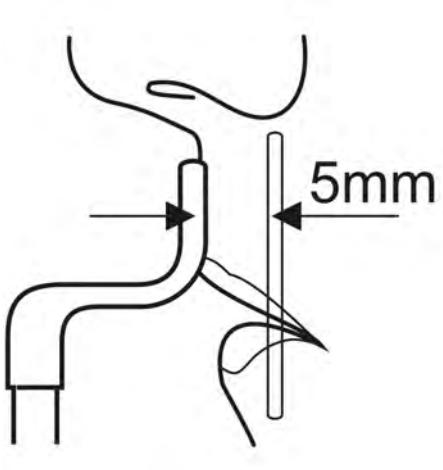


8. The focal trough light indicates the center of the focal trough, which is 10 mm wide at the front. The root apices of the patient's central upper and lower front incisors must be within the focal trough.

   Ask the patient to open their lips so that you can see their teeth. The focal trough light should be positioned slightly in front of the root apices, which for most patients will be in the middle of 3rd tooth (canine).



If the patient is edentulous the focal trough light should be approximately 5mm behind the lip holder when the focal trough position is 0 mm.



NOTE! *If the focal trough light is not positioned as described above, press the focal trough adjustment key(s) to move the focal trough light until it is positioned correctly.*

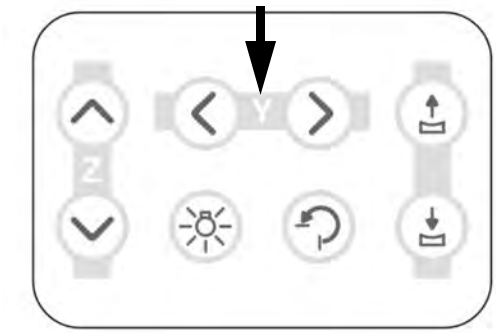
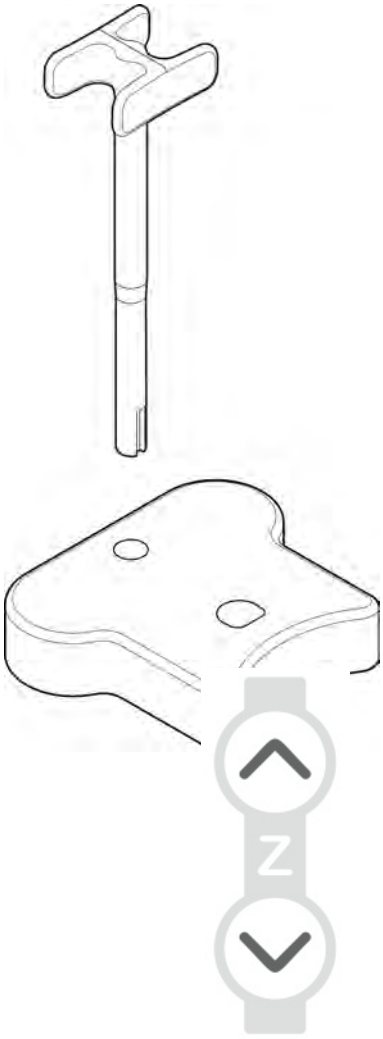


Fig 4.2. Focal trough light position indicator

9. If AES is enabled (green light lit around "A"), press the Return button and wait for the movement to finish. Verify that the suggested exposure values are suitable for the patient. If AES is disabled, set the exposure values manually and press Return to drive the unit into exposure start position (optional).
10. Ask the patient to press their tongue against the roof of their mouth, **swallow** and remain still for the duration of the exposure.



4.3.3.2 TMJ exposure

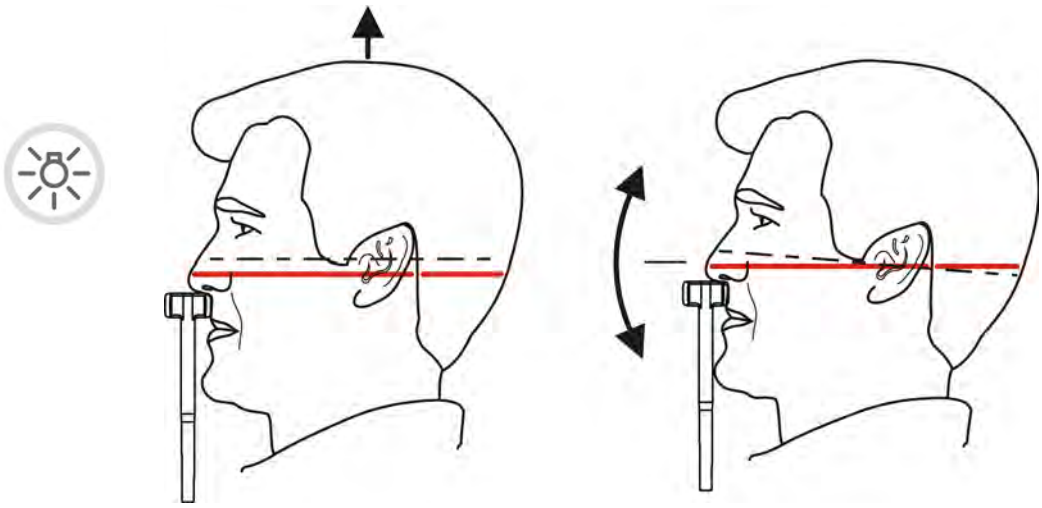
1. Insert the required positioning devices, including the TMJ support. Place the disposable covers.

NOTE! *Use a new disposable cover for every patient.*

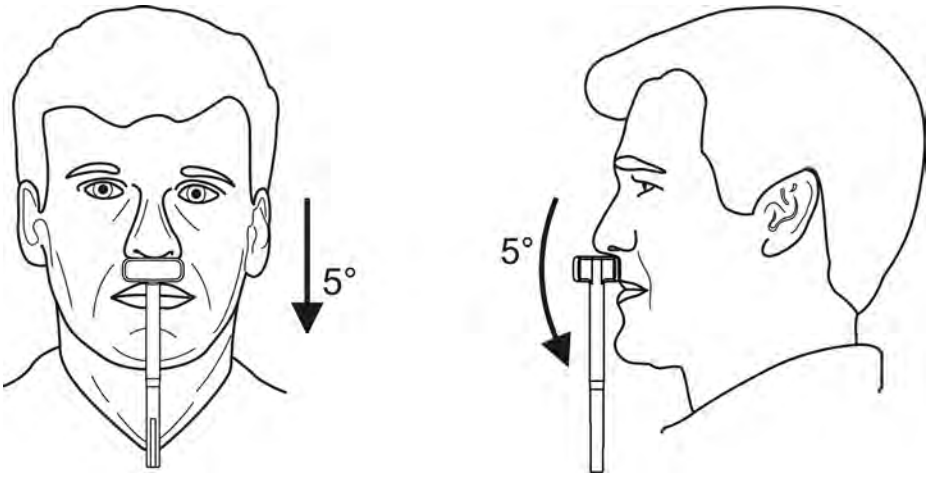
2. Adjust the unit height.

3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Ask the patient to take grip on the handles and set the mouth against the lip holder.

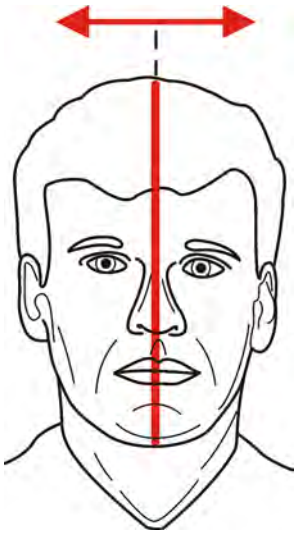
4. TMJ lateral projection: Adjust the height of the Frankfort-Horizontal plane (FH) laser to get the laser light over the orbita porion. Straighten the patient's head if needed.



5. TMJ PA/AP projection: Tilt the patient's head forward.



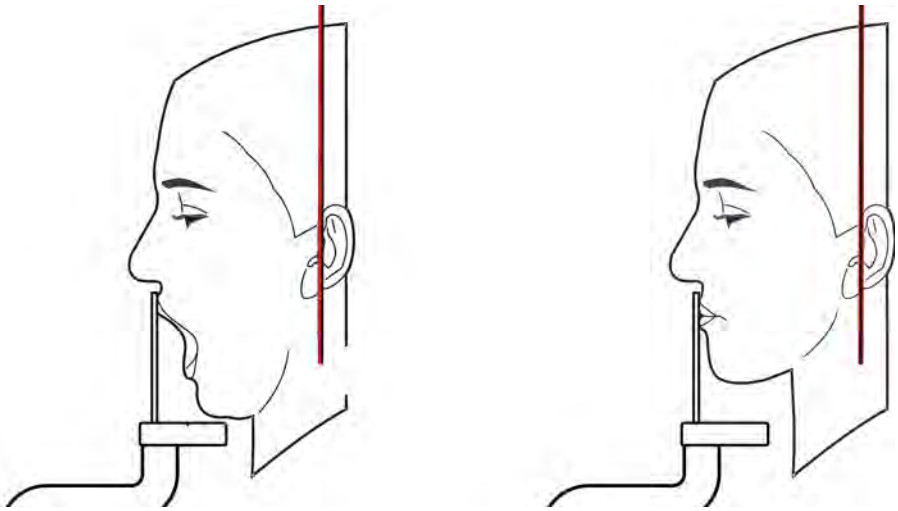
6. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.



7. Close the temple supports by sliding the temple support knob to the right. Adjust the position of the nasion support and push the forehead support in until it touches the patient's nasion.

8. Adjust the position of the TMJ light until it aligns in the middle of condyle.

NOTE! *The condyle moves forward by approximately 10 mm when the mouth is opened"*



9. If AES is enabled (green light lit around "A"), press the Return button and wait for the movement to finish. Verify that the suggested exposure values are suitable for the patient. If AES is disabled, set the exposure values manually and press Return to drive the unit into exposure start position (optional).

10. Ask the patient to press their tongue against the roof of their mouth, swallow and remain still for the duration of the exposure.

4.3.3.3 Maxillary Sinus exposure

1. Insert the the lip holder for sinus imaging.
   Place the disposable covers.

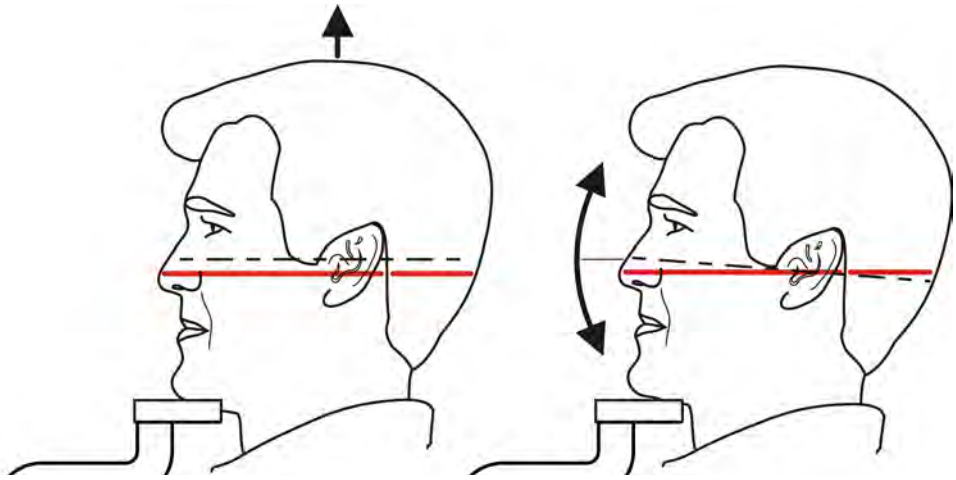
NOTE! *Use a new disposable cover for every patient.*

2. Adjust the unit height.

3. Guide the patient to the unit and instruct to stand as straight and tall as possible. Ask the patient to take grip on the handles and set the mouth against lip holder.

4. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.

5. Adjust the height of the Frankfort-Horizontal plane (FH) laser to get the laser light over the orbita porion. Straighten the patient's head if needed.



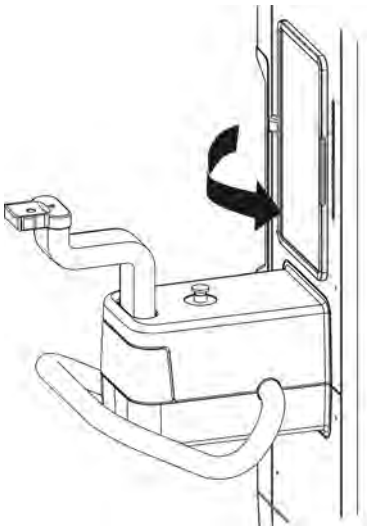
6. Close the temple supports by sliding the temple support knob to the right. Adjust the position of the nasion support and push the forehead support in until it touches the patient's nasion.

7. Adjust the position of the image layer as necessary. The focal trough light should be positioned in the middle of the 3rd tooth or if wanted slightly posterior.

NOTE! *If the focal trough light is not positioned as described above, press the focal trough adjustment key(s) to move the focal trough light until it is positioned correctly.*

8. If AES is enabled (green light lit around "A"), press the Return button and wait for the movement to finish. Verify that the suggested exposure values are suitable for the patient. If AES is disabled, set the exposure values manually and press Return to drive the unit into exposure start position (optional).
9. Ask the patient to press their tongue against the roof of their mouth and remain still for the duration of the exposure.

4.3.4 Taking the exposure



WARNING! *Close the patient positioning mirror before taking any exposures.*

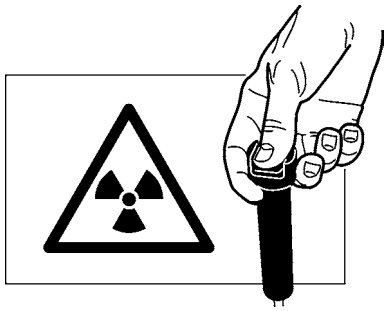
1. Ask the patient to remove any spectacles, dentures, jewellery and hair clips and pins. Ensure that the patient's thyroid glands are protected by a lead apron during exposure.

2. Press **Return**. Check the patient positioning.

   Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Make sure that you can see and hear the patient during the exposure.

NOTE! *In all examinations the user of the x-ray equipment should wear protective clothing. The operator does not need to be close to the patient during normal use. The protection against stray radiation can be achieved by using the hand switch not less than 2 m (7 ft) from the focal spot and the xray beam. Operator should maintain visible contact with the patient and Technical factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.*

NOTE! *If the patient is nervous, or a child, you can demonstrate how the unit works to reassure them. Press the T (Test mode) button and then press and hold the exposure button. The unit will complete an exposure cycle without generating x-rays.*



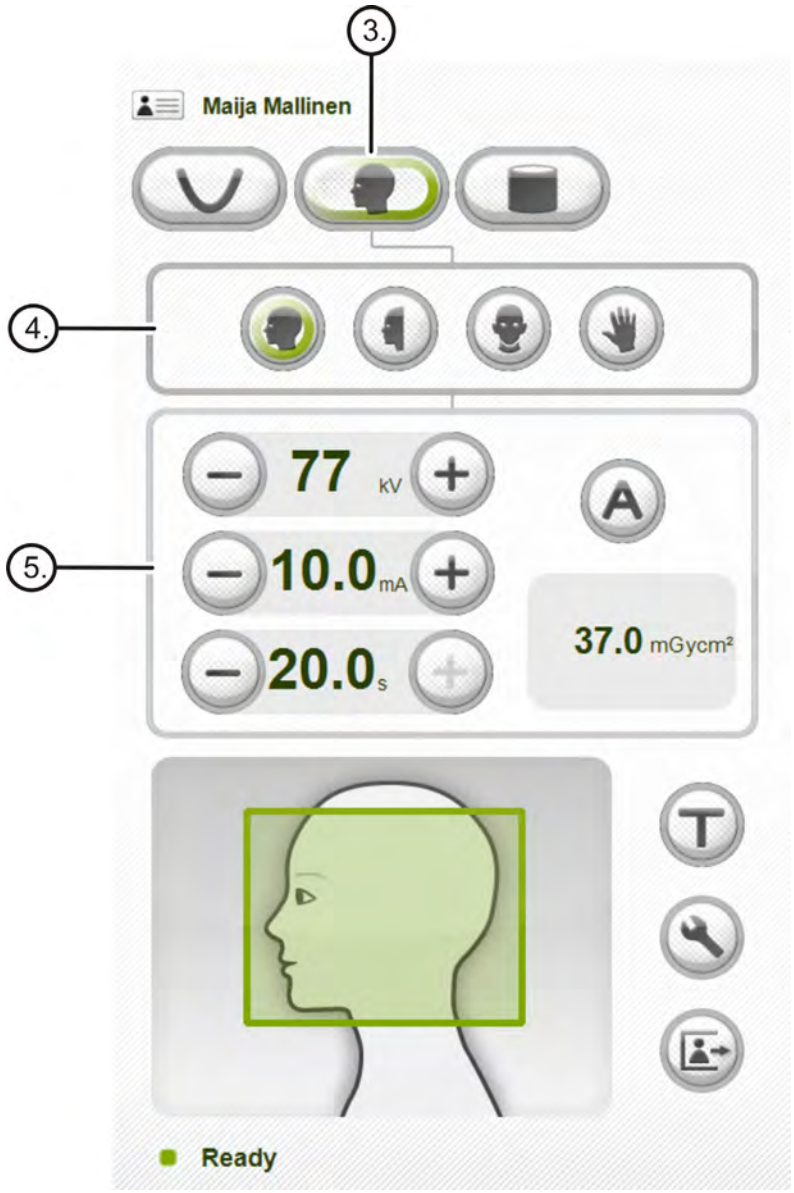
3. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the ClearTouch™ control panel appears.
   The unit rotates around the patient's head and stops. When the rotating unit stops, the exposure has been taken.
4. After the exposure the rotating unit is in 'patient out' position, if the exposure switch has been pressed until all movements have stopped. Release temple supports. Guide the patient out. Remove disposable covers and disinfect the unit.
5. **PC:** The image can be examined using the SCANORA® software. See SCANORA® software user's manual.

4.4 Cephalometric exposures

- Reduced Width lateral projection
- Lateral projection
- PA/AP projection
- Reverse towne projection
- Waters view
- Carpus view (Not in USA and Canada and Canada)

4.4.1 General instructions

1. Move the ceph sensor to the ceph sensor holder in a case of single sensor configuration..
2. **PC**: Click **Image Capture**.
3. Select CEPH.



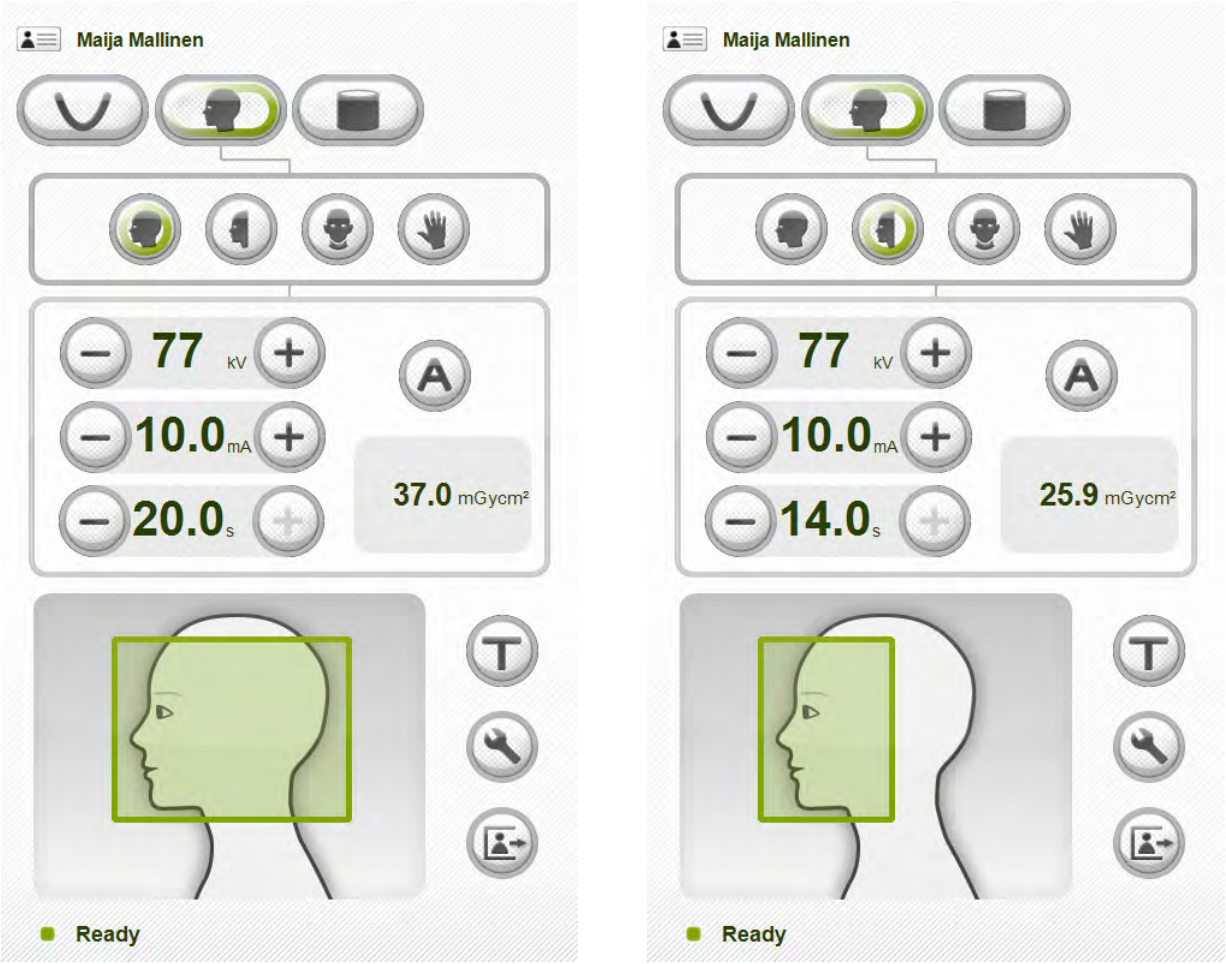
4. Select the imaging program.

5. If AES is enabled (green light lit around "A"), press the Return button and wait for the movement to finish. Verify that the suggested exposure values are suitable for the patient. If AES is disabled, set the exposure values manually and press Return to drive the unit into exposure start position (optional).

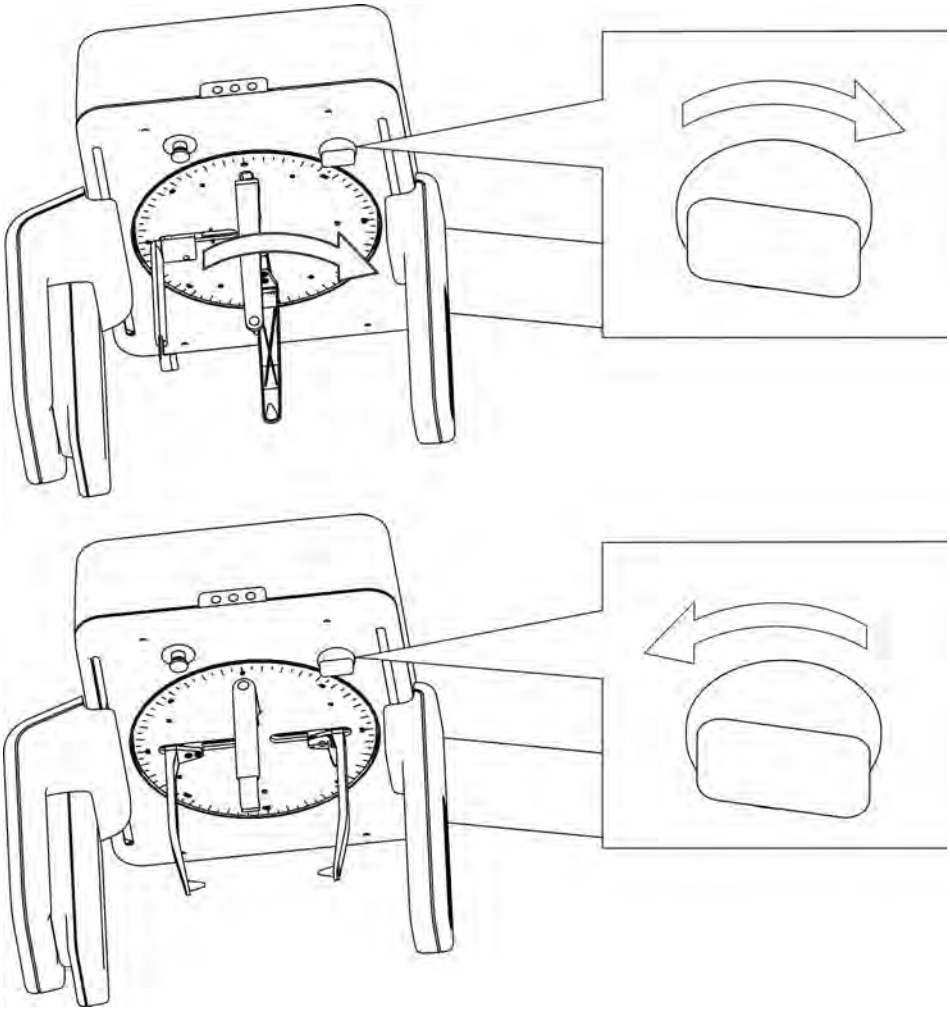
6. Press the Return button to drive the unit to ‘patient in’ position.
7. Ask the patient to remove any spectacles, hearing aids, removable dentures, jewellery and hair clips and pins. Place a protective lead apron on the patient.

4.4.2 Patient positioning

4.4.2.1 Full width and reduced width projection



1. Unlock the lever and turn the ear rods to the lateral projection position. Lock the position.



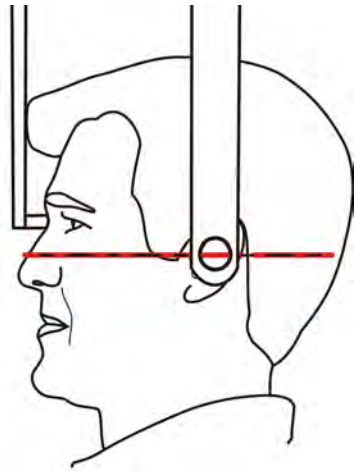
2. Place the disposable covers.

NOTE! *Use a new disposable cover for every patient.*

3. Adjust the unit height.

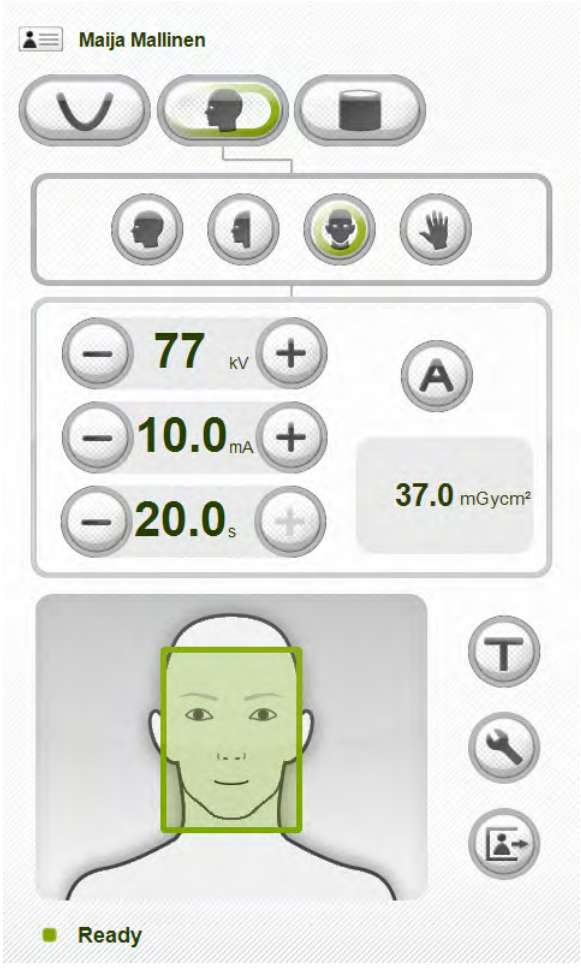
4. Guide the patient to the unit. Instruct the patient to stand as straight and tall as possible under the cephalostat head. Slide the ear rods towards to patient's ears.

5. Adjust the patient head so that the Frankfort-Horizontal plane (FH) and laser light are in same horizontal plane.

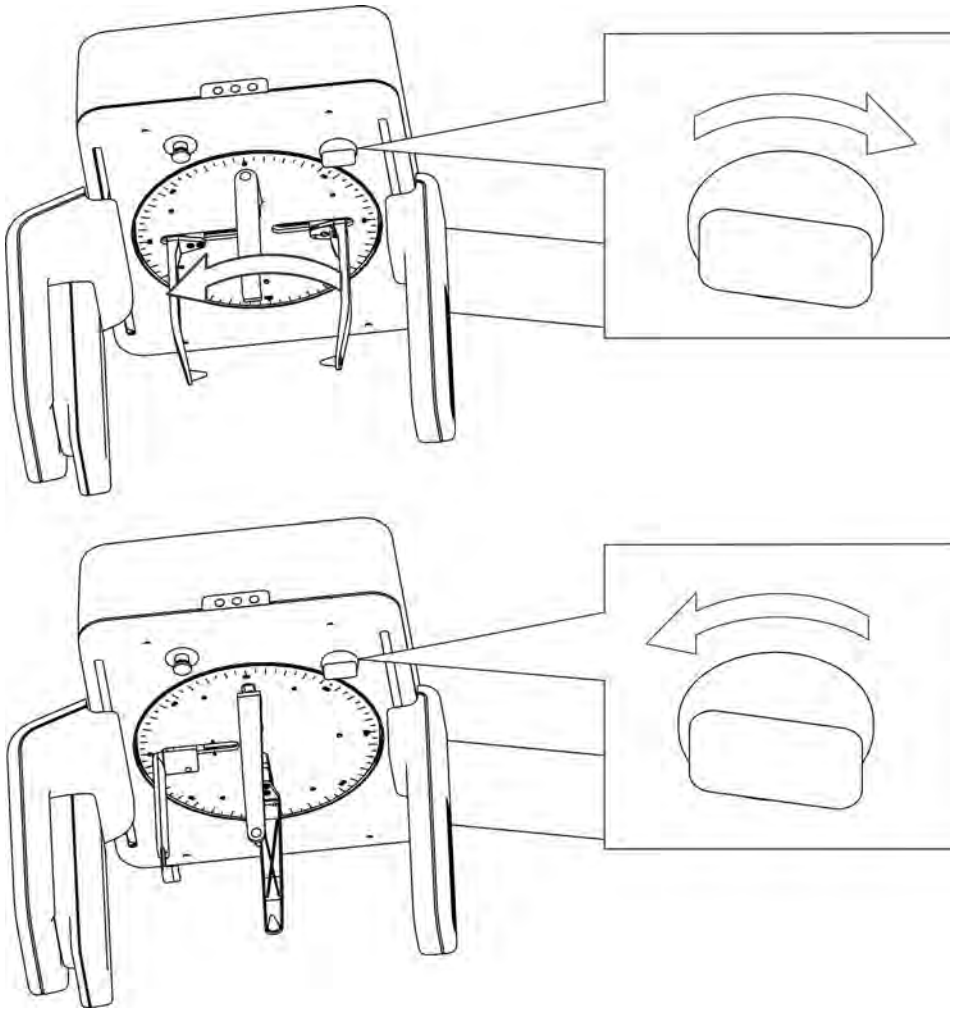


6. Slide nasion support against patient’s nasion.

4.4.2.2 PA projection



1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside.



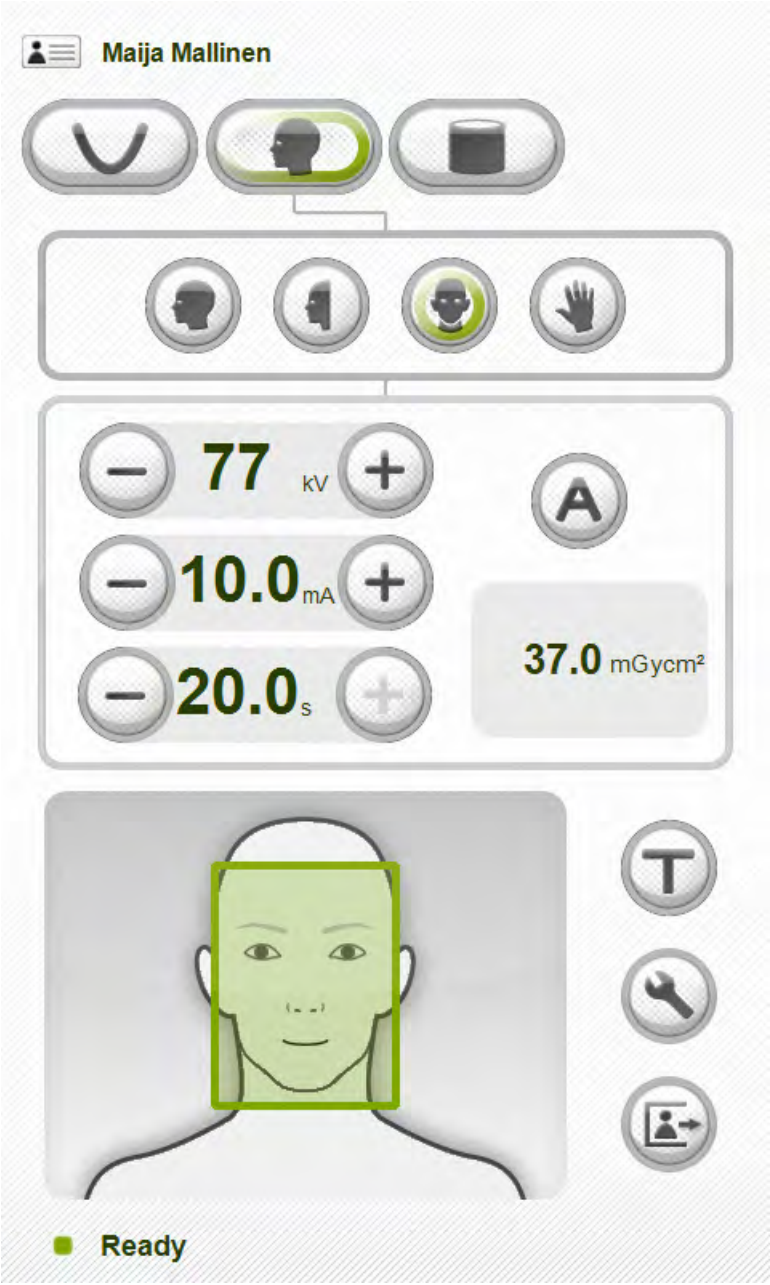
2. Place the disposable covers.

NOTE! *Use a new disposable cover for every patient.*

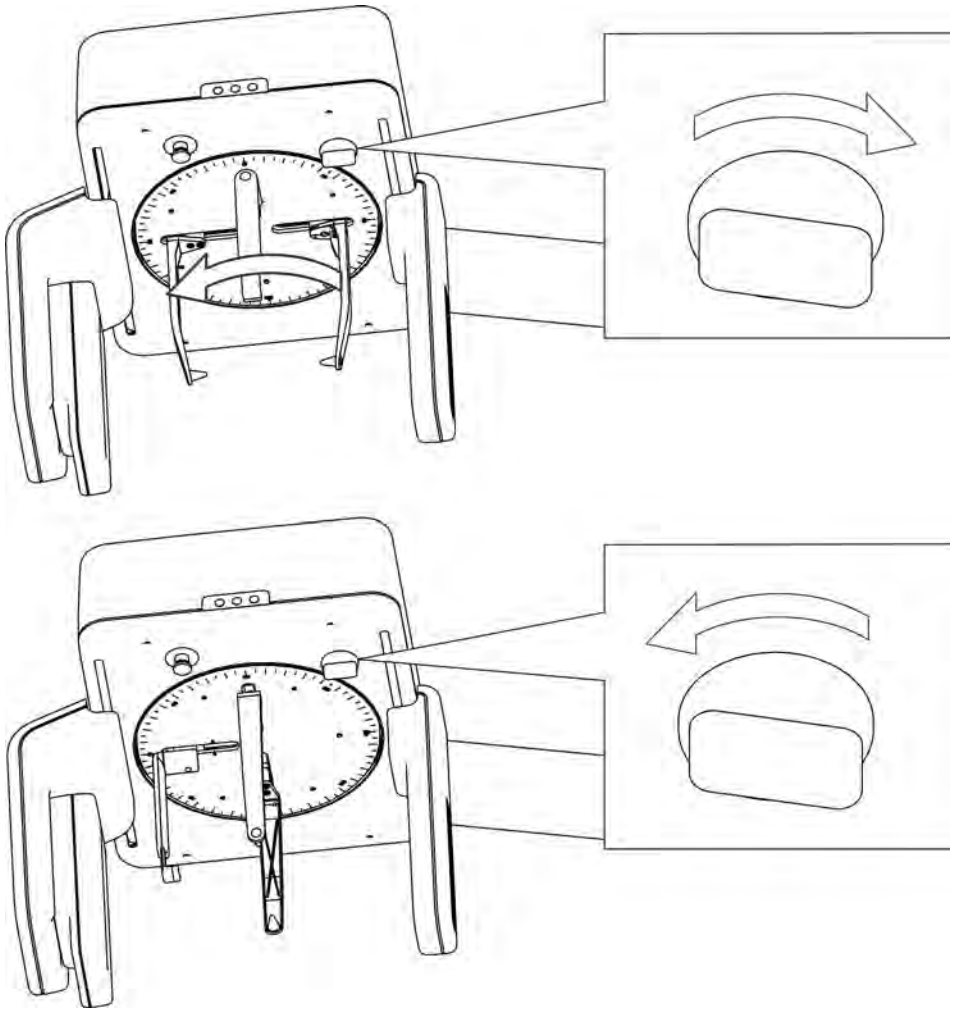
3. Adjust the unit height.

4. Guide the patient to the unit facing the sensor. Instruct the patient to stand as straight and tall as possible under the cephalostat head. Slide the ear rods towards patient's ears.

4.4.2.3 Reverse towne projection



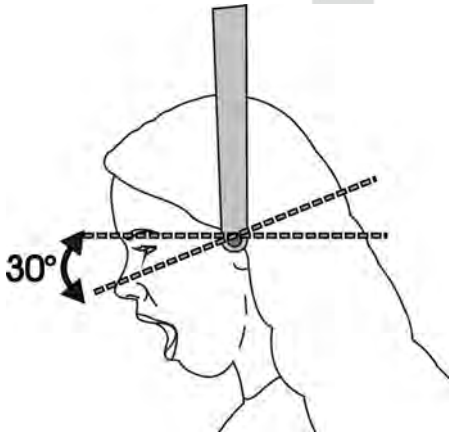
1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside.



2. Place the disposable covers.

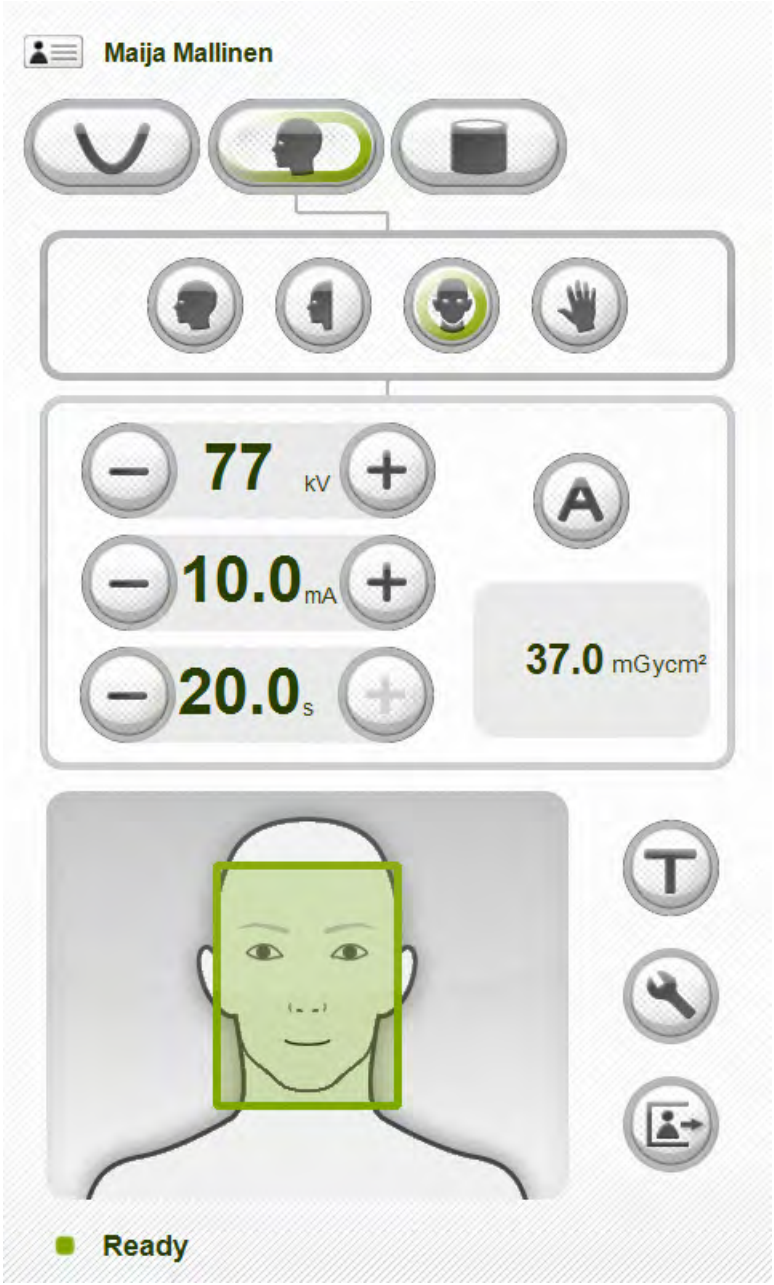
NOTE! *Use a new disposable cover for every patient.*

3. Adjust the unit height.

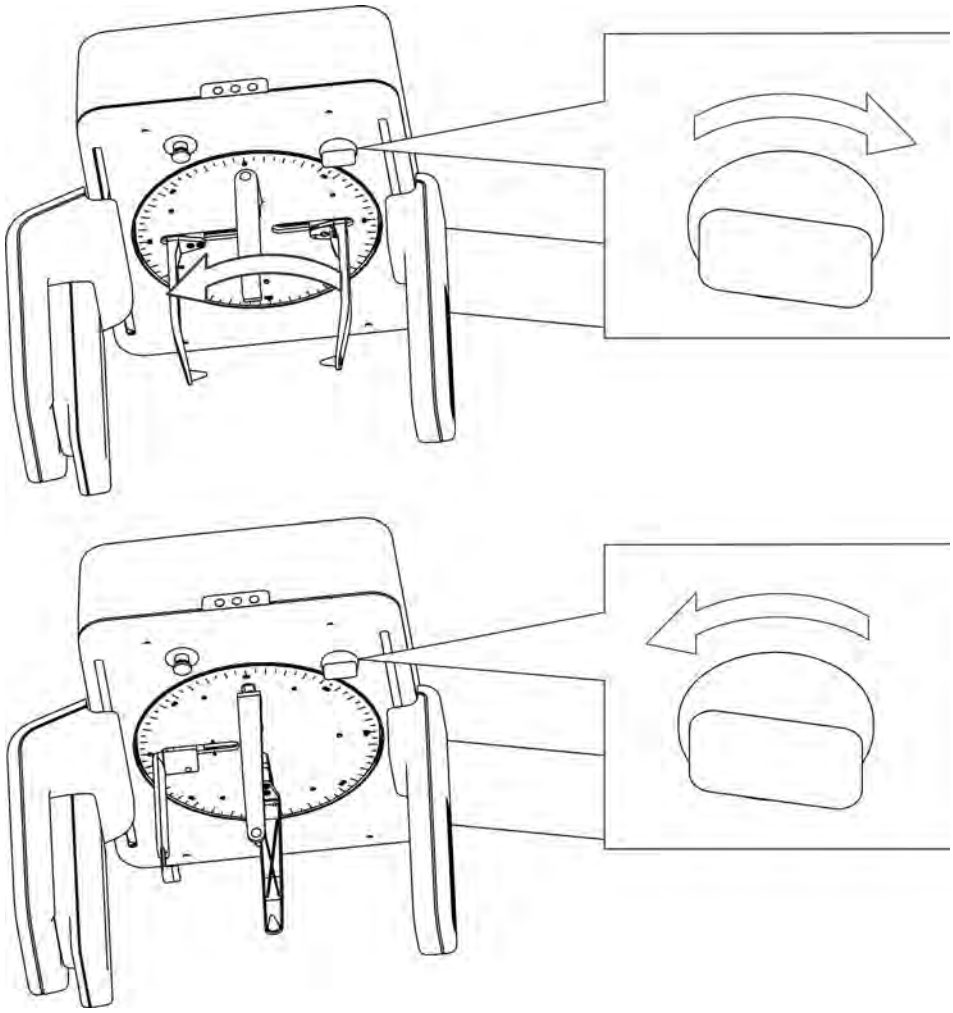


4. Guide the patient to the unit. Instruct the patient to stand as straight and tall as possible under the cephalostat head.
5. Turn the head ventral as reference to the canthomeatal line about 30° below the horizontal plane.
6. Slide the ear rods towards patient's ears.
7. Ask the patient open mouth maximally.

4.4.2.4 Waters view



1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside.



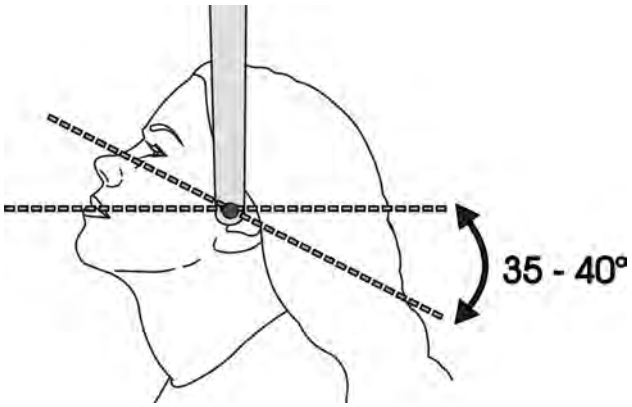
2. Place the disposable covers.

NOTE! *Use a new disposable cover for every patient.*

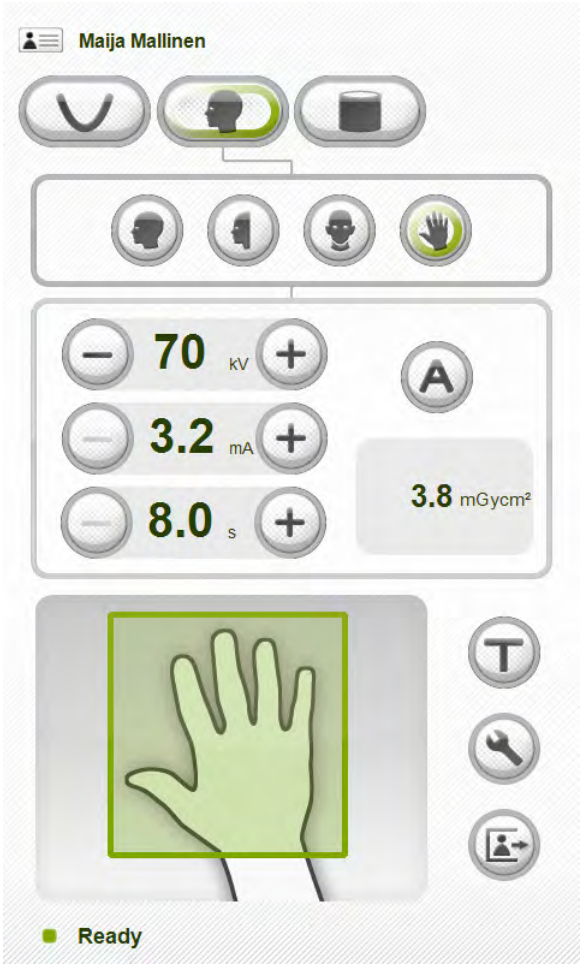
3. Adjust the unit height.

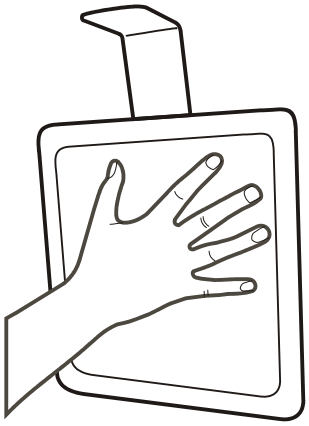
4. Guide the patient to the unit. Instruct the patient to stand as straight and tall as possible under the cephalostat head.
5. Turn the head dorsal as reference to the canthomeatal line about 35-40° above the horizontal plane.
6. Slide the ear rods towards patient’s ears.

7. Ask the patient open or close mouth.



4.4.2.5 Carpus view (Not in USA and Canada and Canada)

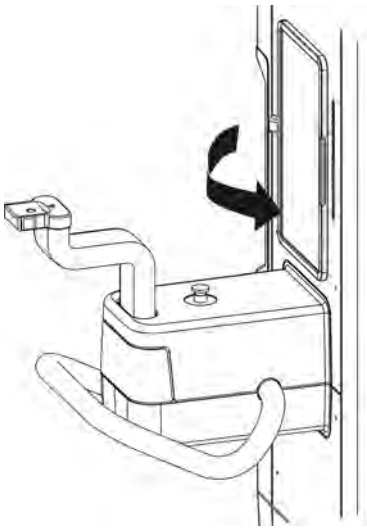




CAUTION! *Before taking Carpus image make sure this imaging method is approved by local authorities of your country.*

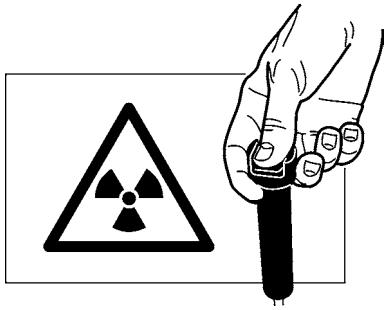
1. Unlock the lever and turn the ear rods to the PA projection position. Lock the position. Tilt the nasion support aside. Place the carpus holder to the nasion support holder.
2. Adjust the unit height if needed.
3. Ask the patient to remove rings and metal objects and to place hand on the carpus holder.

4.4.3 Taking the exposure



WARNING! *Close the patient positioning mirror before taking any exposures.*

1. Ask the patient to remove any spectacles, dentures, jewellery and hair clips and pins. Place a protective lead apron around the patient's neck to protect the patient's thyroid gland from radiation.
2. Protect yourself from radiation by standing behind a suitable x-ray radiation shield. Make sure that you can see and hear the patient during the exposure.



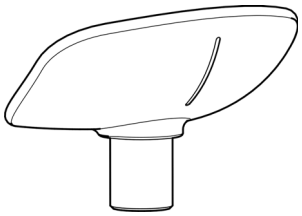
3. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the ClearTouch™ control panel appears.
4. Release the ear rods and guide the patient out. Remove disposable covers and disinfect the unit.
5. **PC:** The image can be examined using the SCANORA® software. See SCANORA® software user's manual.

NOTE! *In all examinations the user of the x-ray equipment should wear protective clothing. The operator does not need to be close to the patient during normal use. The protection against stray radiation can be achieved by using the hand switch not less than 2 m (7 ft) from the focal spot and the xray beam. Operator should maintain visible contact with the patient and Technical factors. This allows immediate termination of radiation by the release of the exposure button in the event of a malfunction or disturbance.*

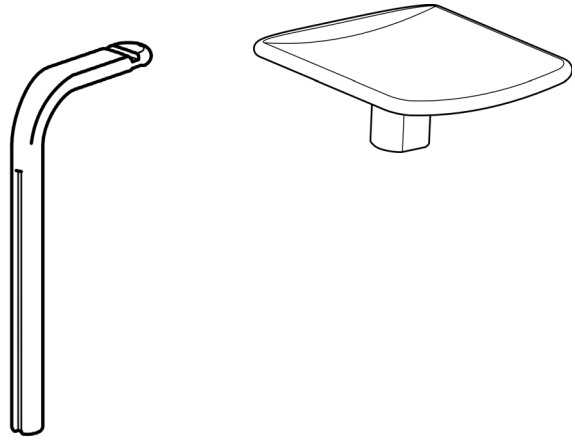
4.5 3D exposures

4.5.1 Positioning devices

Chin cup

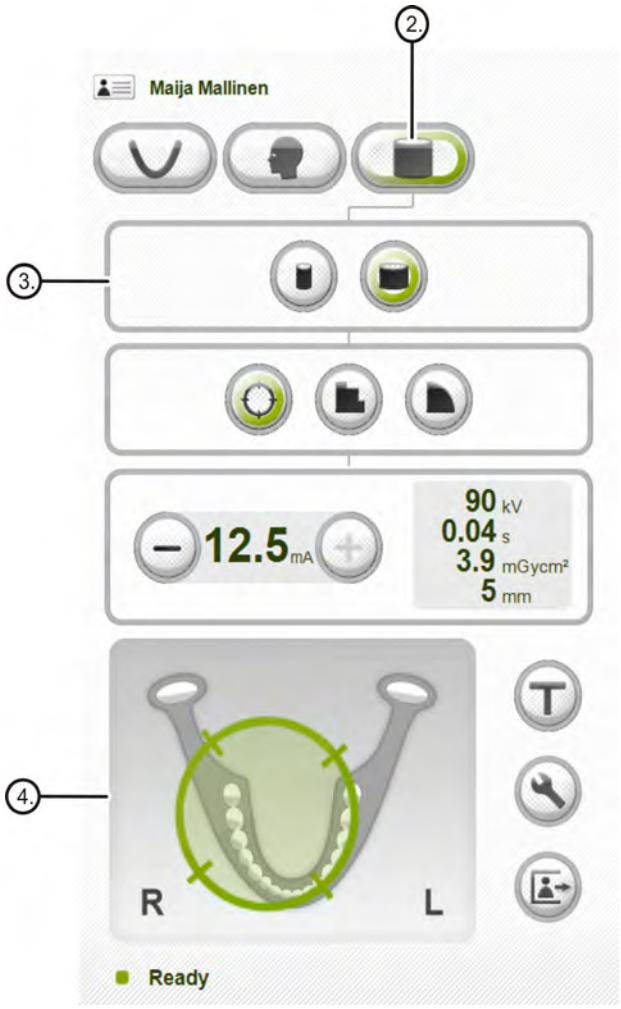


Bite block and chin plane



4.5.2 General instructions

1. **PC:** Click **Image Capture**.
2. Select the 3D modality.



The teeth locations on the 3D dental arch are approximate and are based on average dentition. The exact teeth locations will depend on the patient's individual anatomy.

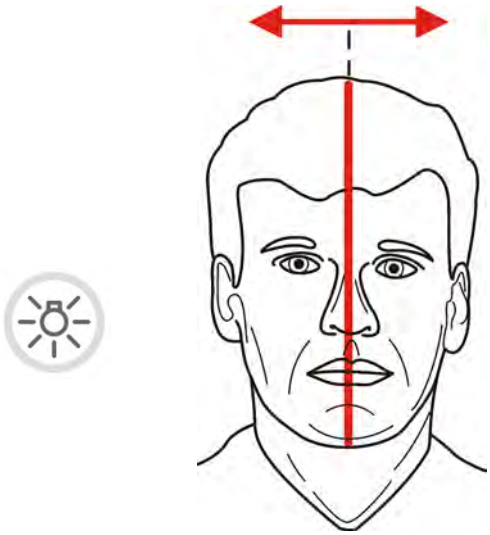
The EasyScout function helps locate the correct dental location of the Field of view.

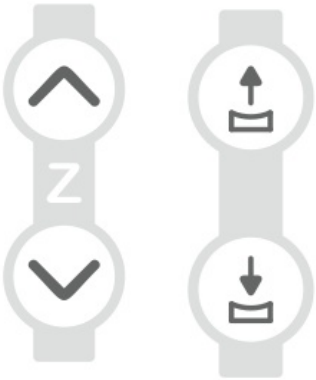
3. Select the Field Of View (FOV):
   XS FOV 61 x 41 mm (Program 1)
   Midi FOV 61 x 78 mm (Program 2) (OPTIONAL)
4. Select the area of interest on the dental arch. The 3D FOV is positioned more accurately by using the scout image mode. The area of interest can be adjusted on the ClearTouch™ control panel after the scout image has been taken.

5. Press the Return button to rotate the unit to ‘patient in’ position.

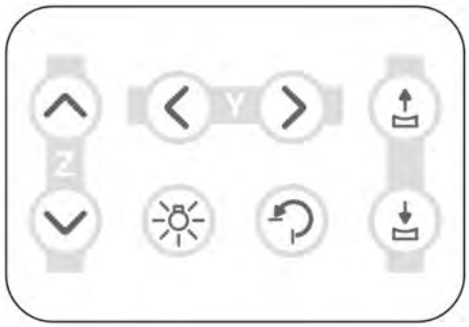
6. Adjust the unit height.
7. Ask the patient to remove any spectacles, hearing aids, removable dentures, jewellery and hair clips and pins.
8. Guide patient to the unit. Instruct patient to stand as straight and tall as possible next to the unit. Patient can also be imaged in sitting position. Ask the patient to take grip on the handles and place chin on the chin cup.

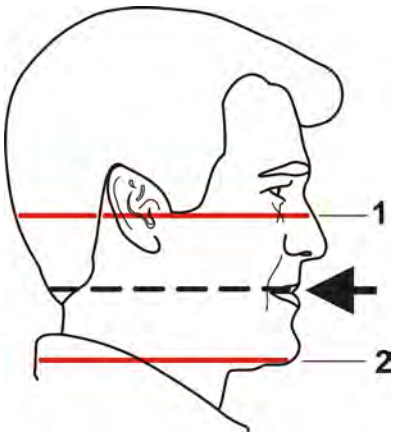
9. Check the position of the midsagittal light. If it is not on the midsagittal plane of the patient, adjust the patient's head.





10. Adjust the unit height and chin rest height to get the area of interest between the top and bottom FOV lights. Position the patient so that the occlusal plane is horizontal.

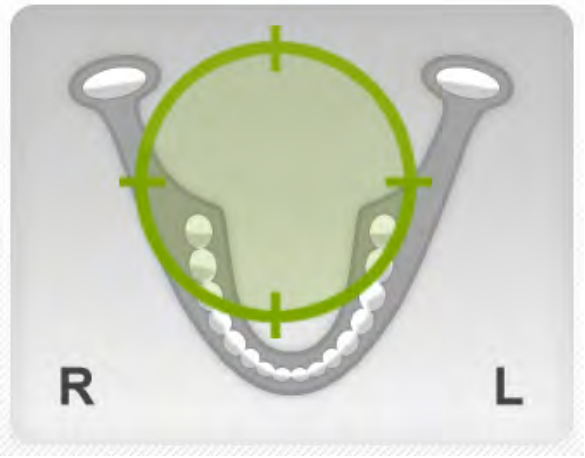




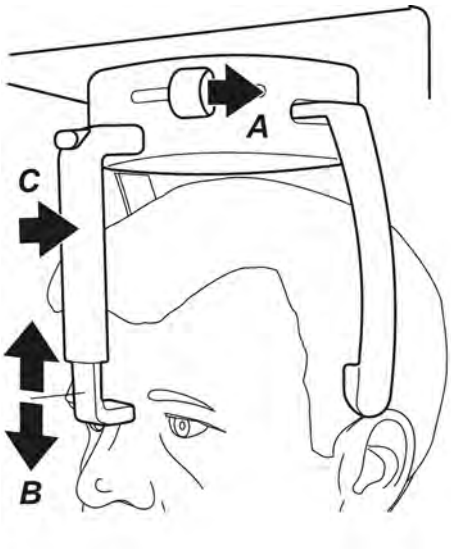
1. Horizontal light, top of FOV
2. Horizontal light, bottom of FOV

NOTE! *Target ROI is always in the middle plane of laser lights.*

11. Select the image area from the dental arch.



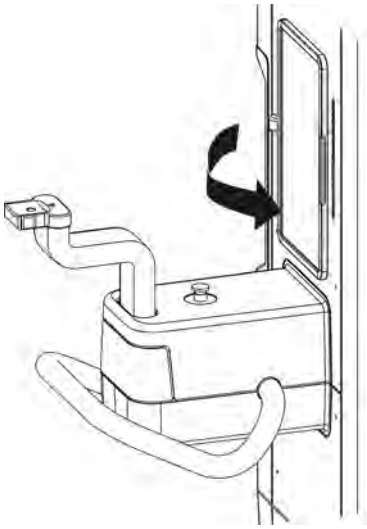
12. Close the temple supports by sliding the temple support knob to the right (A). Adjust the position of the nasion support (B) and push the forehead support in until it touches the patient's nasion (C).



13. Select

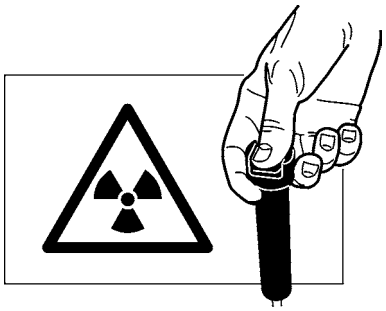
A the Scout image
or
B the Standard or High resolution 3D image

4.5.3 Scout image



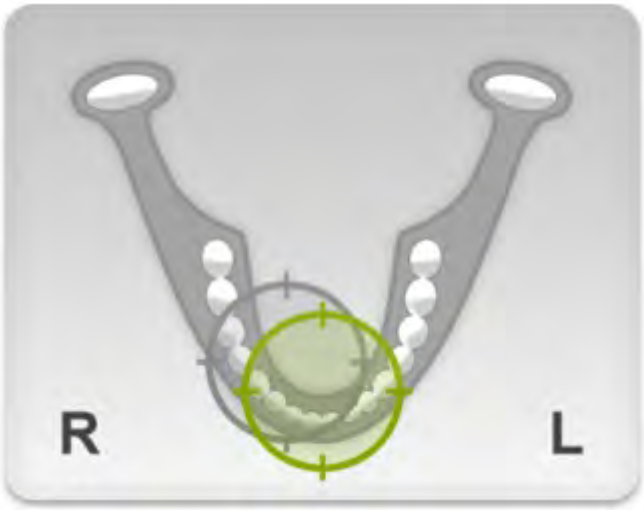
WARNING! *Close the patient positioning mirror before taking any exposures.*

1. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the ClearTouch™ control panel appears.



2. Scout preview image appears to the ClearTouch™ control panel.
3. Fine adjust scout position using the side arrow keys. Press the left lower corner icon to continue.

4. Take a new scout or
   save current and continue to 3D image.
5. Previous FOV position is shown as gray circle and new position is showed as green circle.



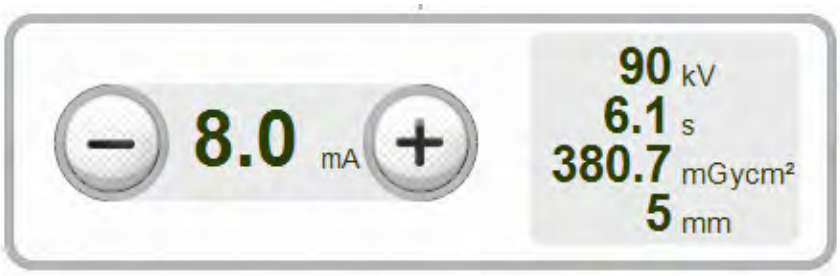
NOTE! *Gray circles remain in control panel until you change the patient.*

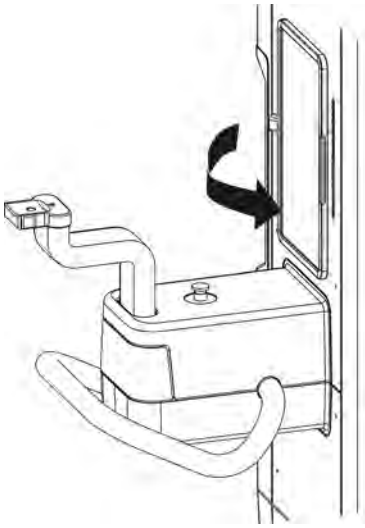
4.5.4 3D image

1. Select the Standard or

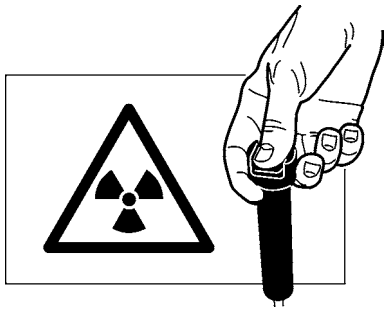
   High resolution .

2. Select mA.





WARNING! *Close the patient positioning mirror before taking any exposures.*



3. Press and hold down the exposure button. During the exposure you hear an audible signal and the exposure warning symbol on the ClearTouch™ control panel appears.

4.6 Warnings and error messages

The unit responds to error situations by showing a dialog box containing an error code and descriptive text on the touch screen.

When an error code appears on the display the unit will stop working and cannot be operated while the error code is on the display. In less severe cases a warning message will be displayed, leaving the unit operable.

4.6.1 Acknowledging errors

Most errors may be acknowledged by closing the dialog box the error is reported in. Some errors require the unit to be rebooted. If such an error occurs, or if the unit fails to operate as described in the user's manual, switch the unit off, wait a few seconds and switch the unit on again.

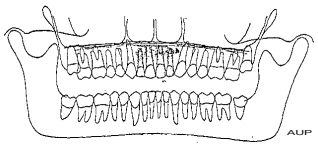
4.6.2 Image transfer errors

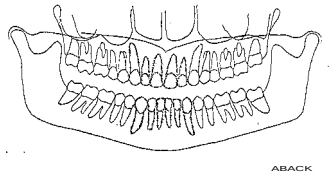
If an image is not transferred successfully to the PC, close and then reopen the dental imaging software and/or restart the PC. DO NOT restart the unit as this will erase any image that is stored in the unit memory and this retrievable image will be lost.

5 Troubleshooting

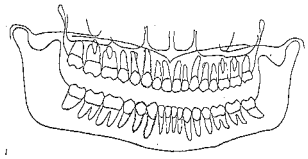
High quality images with sharp contrast and good detail provide optimum diagnostic information. Images with less quality are usually the result of one or more common problems.

5.1 Patient positioning

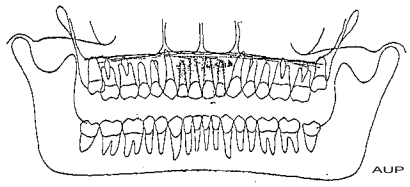
Problem	Possible cause	Remedy
Incisors and canines narrow and unsharp. Overshadow in molar and premolar areas. Rows of teeth are compressed. 	1. Occlusal correction of focal trough set too far posterior 2. Image layer laser light not obeyed 3. Bite block was not used	1. Check patient positioning with laser light lines and occlusion correction buttons 2. Check patient positioning with laser light lines and occlusion correction buttons 3. Insert bite block

Problem	Possible cause	Remedy
Incisors and canines wide and unsharp. Rows of teeth widened. 	1. Occlusal correction of focal trough set too far anterior 2. Image layer laser light not obeyed 3. Bite block was not used	1. Check patient positioning with laser light lines and occlusion correction buttons 2. Check patient positioning with laser light lines and occlusion correction buttons 3. Insert bite block

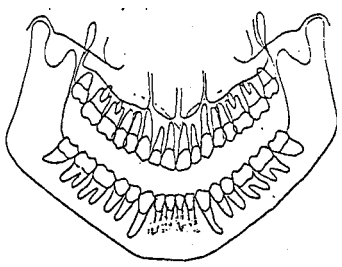
Problem	Possible cause	Remedy
Teeth appear wider on one side and narrower on the opposite. Ramus widths are different on opposite sides.	1. Midsagittal line not obeyed 2. Patient's head not in center position	1. Check patient's mid sagittal plane with laser light line 2. Check that patient's head is centered, and that the head support side clamps where closed to keep the head straight.



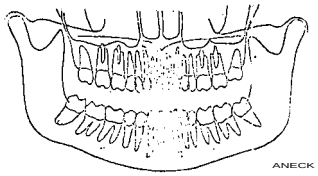
Problem	Possible cause	Remedy
The shadow of hard palate is exposed over maxillary molars. Row of teeth has a wavy appearance. TM joints are exposed outward. Image is not "smiling". Mandible is imaged sharper than maxilla.	Patient head tilted back	Check FH plane



Problem	Possible cause	Remedy
Rows of teeth curved upwards. Mandibular incisors are unsharp. TMJ joints exposed high and are often cut off from the image. Image is "smiling" too much.	Patient head tilted forward	Check FH plane



Problem	Possible cause	Remedy
Middle area of the image too bright and unsharp. Spine shadow.	Patient's neck was not stretched	Stretch patient's neck



Problem	Possible cause	Remedy
Black shadow over maxillary teeth apex area.	Tongue was not against the roof of palate.	Ask patient to swallow and place tongue against the roof of palate during the exposure.

Problem	Possible cause	Remedy
TMJ's exposed on different heights on image. Bilateral distortion in molar and premolar regions.	1. Patient tilted to one side 2. Midsagittal laser light line not obeyed.	1. Check midsagittal plane and center patient's head. 2. Check midsagittal plane and center patient's head.

Problem	Possible cause	Remedy
Rows of teeth exposed too high. TMJ's cut off.	1. Chin was not resting on chin support 2. Patient positioned too high	1. Check patient positioning and type of bite rod. 2. Check patient positioning and type of bite rod.

Problem	Possible cause	Remedy
Rows of teeth exposed too low. Mandible not exposed completely to the image.	Chin rest was not used with bite rod.	Install chin rest.

5.2 Image appearance

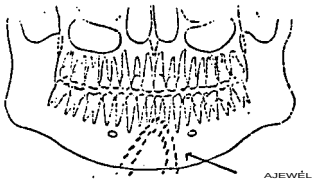
Problem	Possible cause	Remedy
Images are too light	1. SCANORA® software: Contrast and brightness not optimum 2. SCANORA® software: Gamma not set correctly	1. Adjust contrast and brightness. 2. Select a more fitting histogram type and check gamma setting.

Problem	Possible cause	Remedy
Images are too dark	1. SCANORA® software: Contrast and brightness not optimum. 2. Manual Technical factors used too high.	1. Adjust contrast and density. 2. Decrease Technical factors.

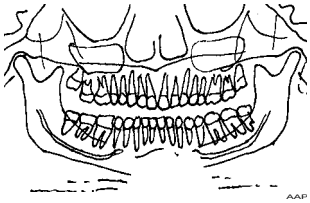
Problem	Possible cause	Remedy
Lack of image contrast	1. SCANORA® software: Contrast and brightness not optimum. 2. kV used is too high. 3. Gamma value is not correct for the monitor being used.	1. Adjust contrast and brightness. 2. Lower the kV setting. 3. Adjust Gamma value

5.3 Artefacts

Problem	Possible cause	Remedy
Irregular, bright shadows or artefacts	Patient is wearing metal objects, such as earrings, necklace etc.	Ask patient to remove objects.



Problem	Possible cause	Remedy
An unexposed area is shown down in the lower middle section of the image.	Lead apron misplaced.	Check the lead apron positioning.



Problem	Possible cause	Remedy
Partial lack of detail and motion artefacts. Irregular vertical bright lines on image.	Patient has moved during the exposure.	Retake the image.

Problem	Possible cause	Remedy
Vertical dark lines on image.	Patient's shoulder in touch with machine parts.	Check patient positioning.

Problem	Possible cause	Remedy
Patient's right side tooth are not exposured.	Exposure button released prematurely.	Retake the image.

Problem	Possible cause	Remedy
Right and left image sides are uncomplete. TMJ's are not shown.	Orthogonal procedure was mistakenly used.	Select correct panoramic procedure.

Problem	Possible cause	Remedy
A light horizontal line on QC image.	Bite block was left on place.	Remove the bite block and retake QC image.

Problem	Possible cause	Remedy
Horizontal lines on image.	Sensor problem.	Consult the dealer.

Problem	Possible cause	Remedy
CEPH: Lateral view has 2 ear holder pins.	1. Cephalostat lock not locked	1. Lock it
	2. Ear holders misaligned	2. Call service

5.4 Unit operation

Problem	Possible cause	Remedy
Back of the patient's head is touching the x-ray tube during the exposure.	1. Patient's head inclination not correct 2. Patient is too big for the unit. 3. Patient has slumped.	If the image is not acceptable then 1. Check the head position and retake the image. 2. Check the patient positioning. Make the exposure even though the head may touch the tube head. 3. Check the patient positioning. Make the exposure even though the head may touch the tube head.

Problem	Possible cause	Remedy
Patient's shoulders are touching the x-ray tube or sensor.	Patient is too big for the unit. Wide and high shoulders.	Reverse patient's hands on handles: left to right side handle and vice versa.

6 Maintenance

6.1 Maintenance procedure

The maintenance procedure described below shall be seen as a minimum requirement and can be made more stringent to comply with regulations regarding the use and maintenance of dental x-ray devices that are in force in the country in which the unit is installed.

Annual maintenance

An annual maintenance procedure must be carried out at least once a year by qualified service personnel. Contact your local distributor for details.

Calibration intervals

To keep the image quality at best possible level, calibrations and quality checks shall be carried out at regular intervals according to the table below.

Modality	Minimum requirement	Recommendation
3D	Two (2) times annually	Four (4) times annually
Panoramic	Annually during normal maintenance	Two (2) times annually
Cephalometric	Annually during normal maintenance	Two (2) times annually

NOTE! *The calibrations mentioned in this manual can be done by the user or qualified service personnel.*

6.1.1 Performing calibrations

Calibrations and quality checks are performed by taking exposures of calibration tools. The system does needed adjustments according to the image data captured. For panoramic and cephalometric quality checks the quality is visually evaluated by the operator.

Resulting from the each calibration is an image containing calibration results, telling the operator how to proceed with the calibration and adjustment procedure. In addition to the calibration name (e.g. Adjustment panCol) the images contain image data sampled during the calibration,

adjustment instructions and a "Passed / Not Passed / Failed" calibration status.

- **Passed** means that the calibration program is successfully done. Move on to next calibration.

- **Not passed** means that adjustment is still needed. Follow the instructions contained in the image (if any) and take another exposure. Some calibration programs are iterative and demand a few repetitions.

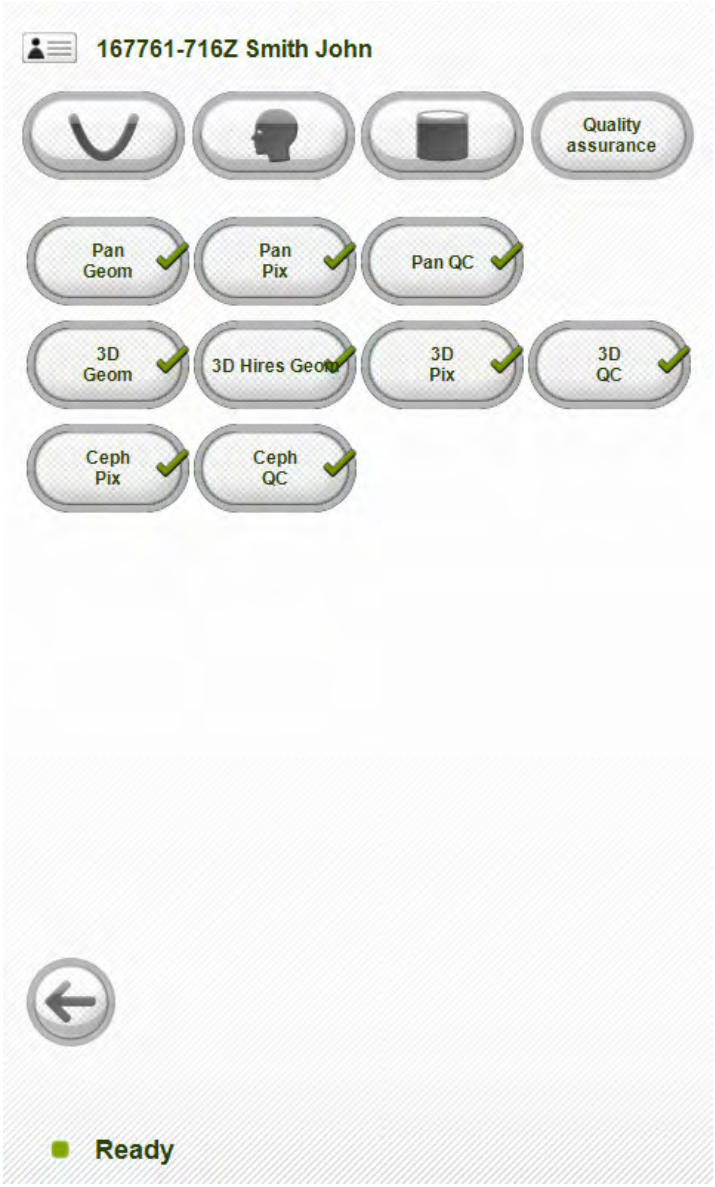
- **Failed** means that the system could not decide what adjustment should be done in order for the calibration to succeed. This calibration status is always the result of some error condition. Contact service if the problem persists after restarting the unit and PC.

6.1.2 Preparing for calibration

1. Close the head support and lock it in its upmost position.
2. Switch the PC and unit on.
3. **PC:** Open the dental imaging sofware and then open a patient (card) and give it and identfiable name, for example: calibration (refer to the user's manual supplied with the dental imaging software for more information).

4. **PC:** Click the image acquisition button to activate image capture.

5. Touch **Settings** on the Touch screen display.
6. Select **Quality assurance**.
   The calibration display appears.

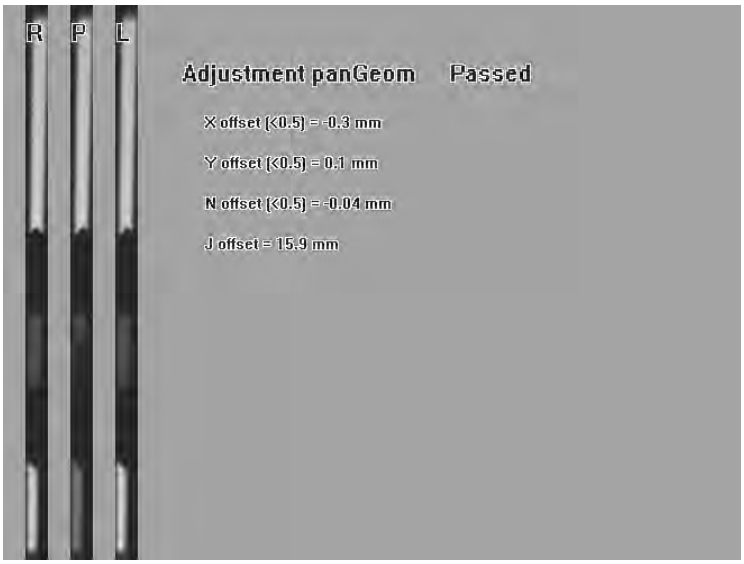


6.1.3 Panoramic calibration and quality check

6.1.3.1 Panoramic geometry calibration

1. Select the program.
2. Press the return button.

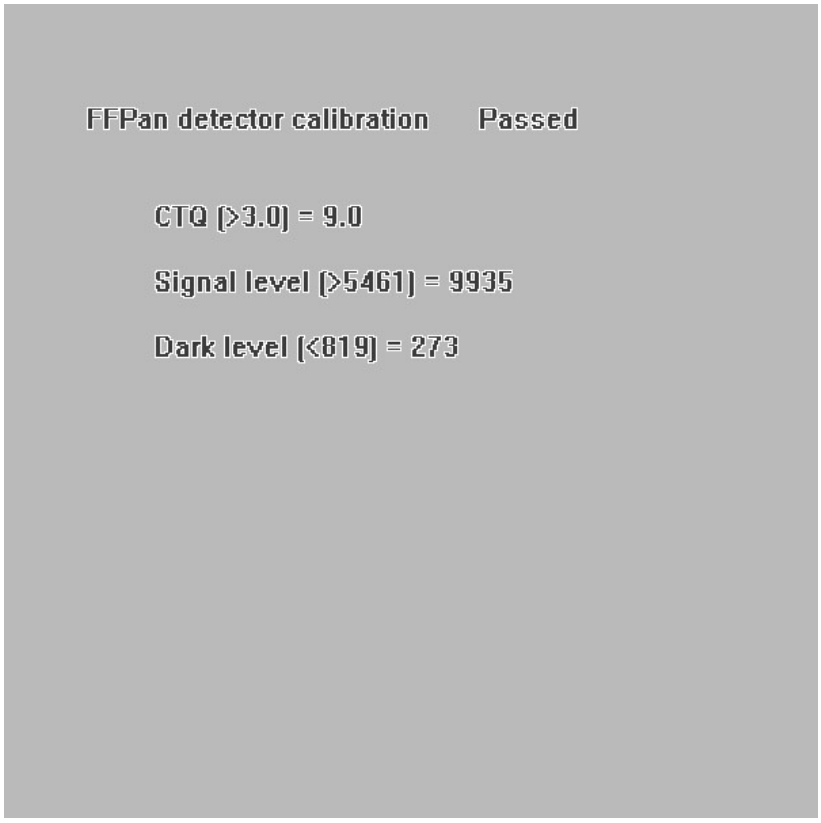
3. Install the double cone calibration tool.
4. Take an exposure. Repeat the calibration until calibration result "passed" is achieved.



6.1.3.2 Panoramic pixel calibration

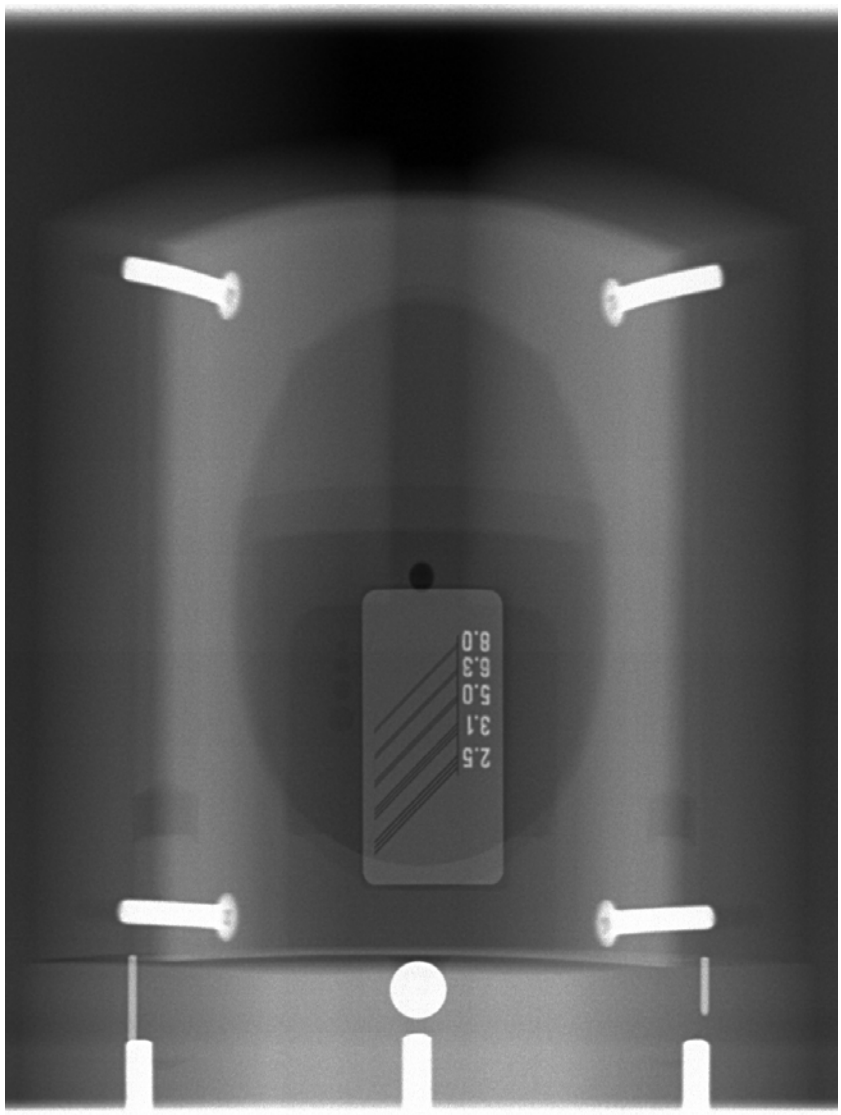
1. Remove calibration tools.
2. Select the program.
3. Press the return button.

4. Take an exposure.



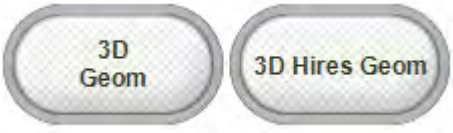
6.1.3.3 Panoramic Quality Check (OPTIONAL)

1. Attach a line pair calibration tool on the ball pin phantom to the chin support.
2. Select the Pan QC program.
3. Press the return button.
4. Take an exposure.
5. Visually evaluate the result using the installed imaging software.



6.1.4 3D calibration and quality check

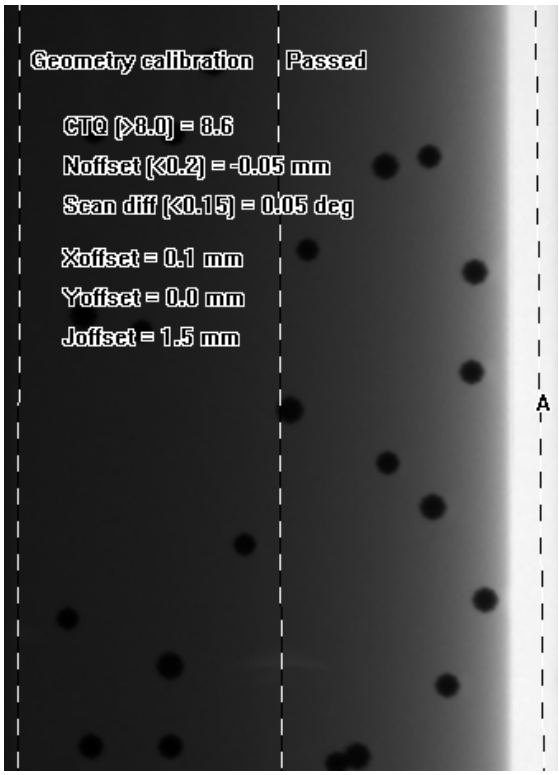
6.1.4.1 3D geometry calibration



1. Attach the base of the phantom to the chin rest holder. Level it with the bubble.
2. Select the program. There is a calibration procedure for both 3D imaging modes, standard and High

resolution. Standard geometry calibration has to be done first.

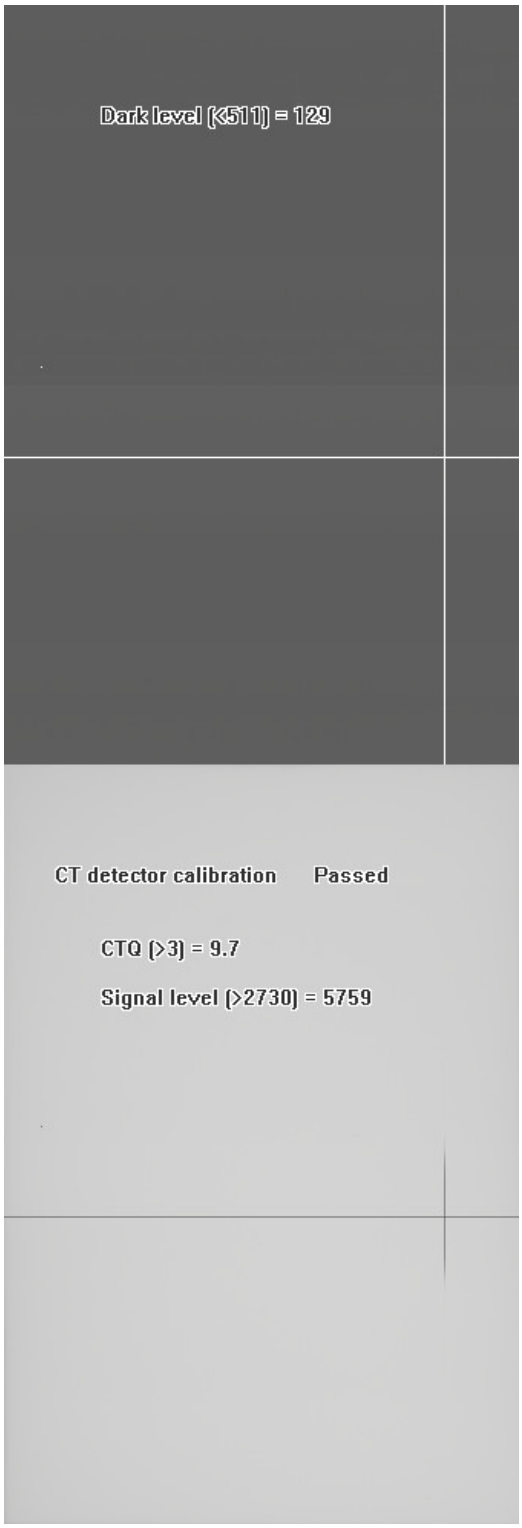
3. Press the return button.
4. Install the 3D calibration phantom.
5. Take an exposure. Repeat the calibration until calibration result "passed" is achieved. This calibration is only needed with 3D units.



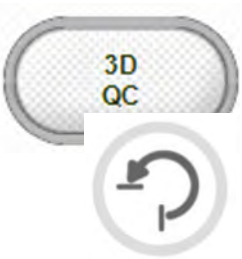
6.1.4.2 3D pixel calibration

1. Remove calibration tools and base of the phantom.
2. Select the program.

3. Press the return button.
4. Take an exposure.



6.1.4.3 3D Quality Check



1. Attach base of the phantom and the QC phantom to the unit.
2. Select the 3D QC program.
3. Press the return button.
4. Take an exposure.

5. Review, with 3D viewing software from the axial view by scrolling the slices the info about calibration result. The resulting image contains information on whether the quality check was passed. Repeat until quality check is passed.

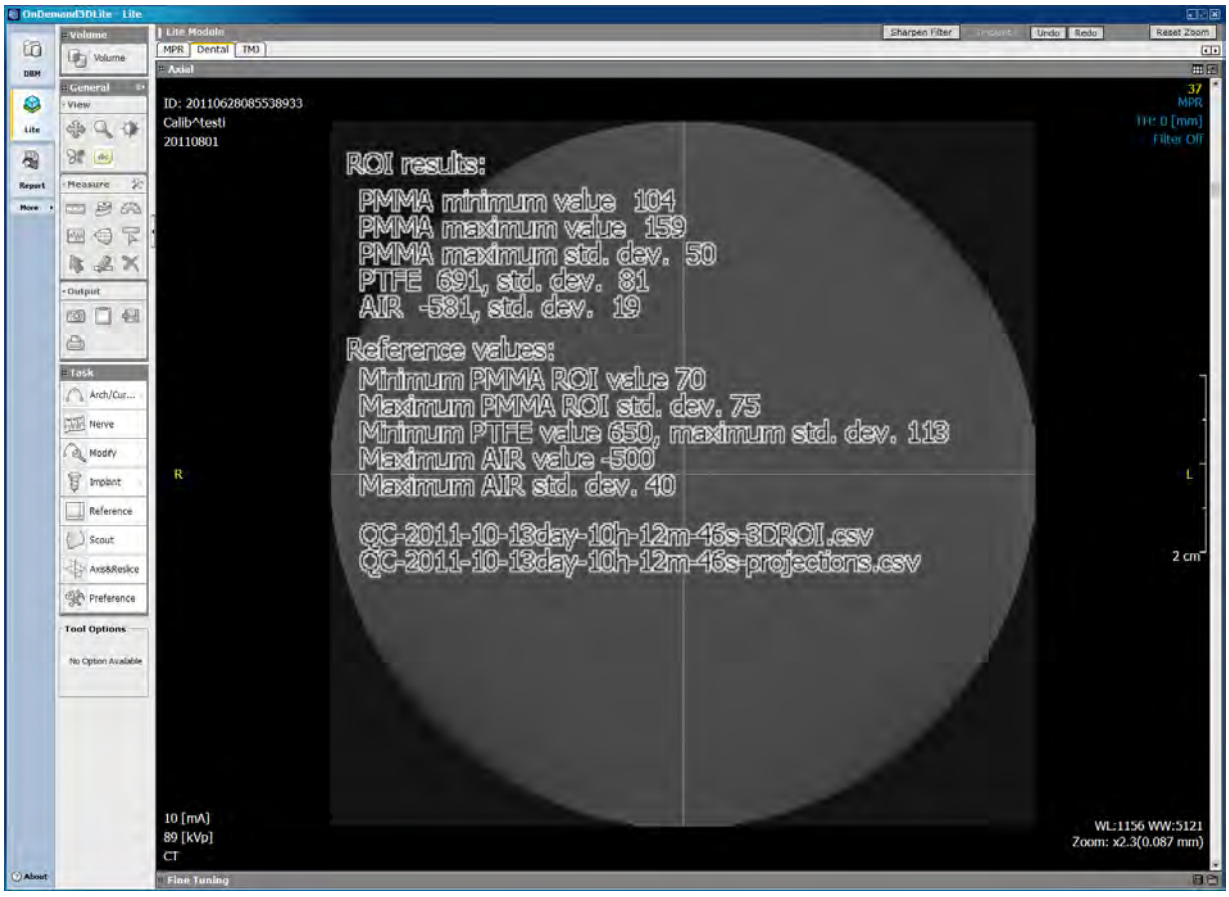


Fig 6.1. 3D calibration results

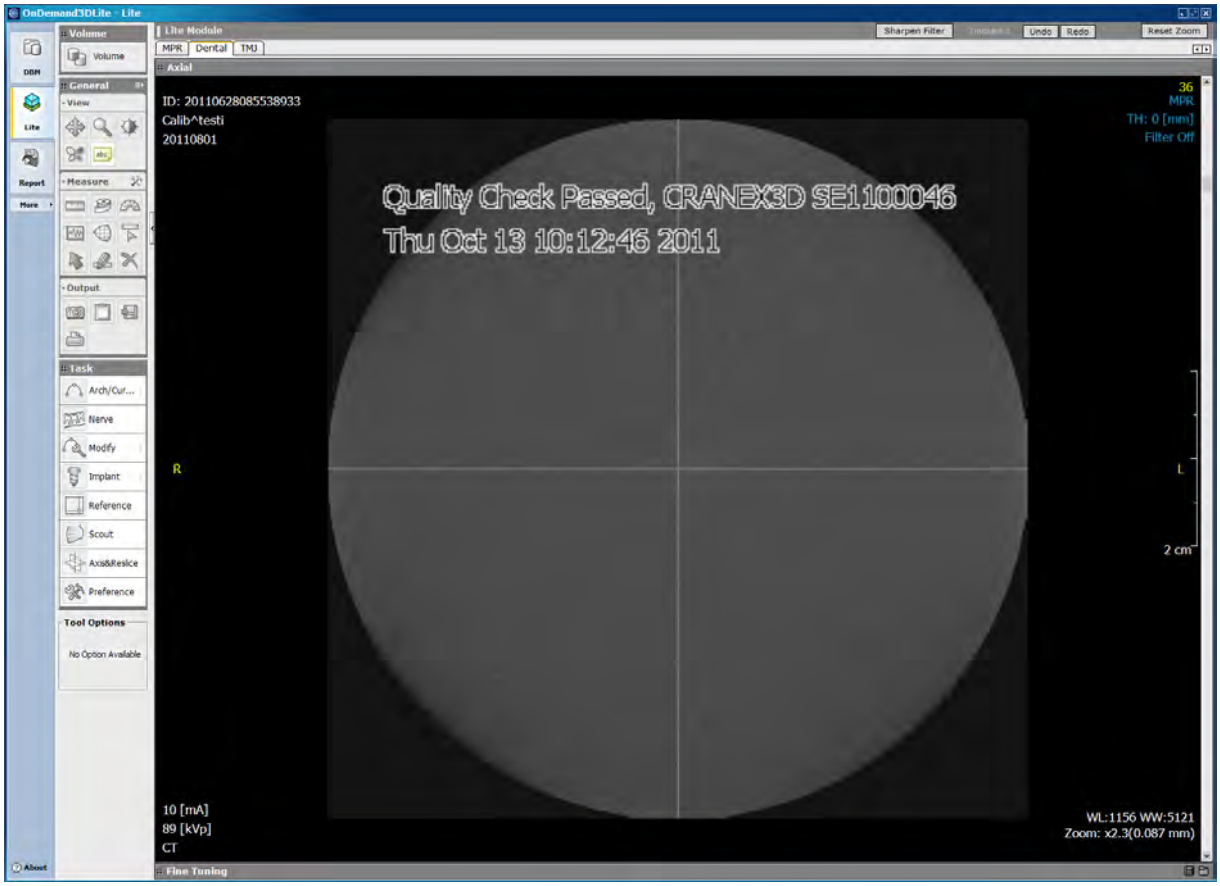


Fig 6.2. Quality Check Passed

6.2 Changing the fuses

Main fuses are located next to the on/off power switch. Push inward on the fuse base and twist it counterclockwise with a screwdriwer. The fuse with the base comes out.

Remove the fuse from the base and replace it with the new one. Repeat this with each blown fuse. Fasten both fuses by pushing the base in and twisting it clockwise with a screwdriver.

Use only appropriate fuses:

- Line voltage 220-240 Vac: 326 Littelfuse 10A (slow blow) or Cooper Bussman MDA-10 (time delay)

- Line voltage 100-120 Vac: 326 Littelfuse 15A (slow blow) or Cooper Bussman MDA-15 (time delay)

6.3 Cleaning and disinfecting the unit

CAUTION! *Switch the unit off or disconnect it from mains before cleaning the unit. If you use a spray cleaner do not spray into any ventilation grills. Do not allow water or other cleaning liquids to enter the unit interior since these may cause short-circuits or corrosion. The unit should be cleaned after every usage.*

Unit surfaces

All surfaces can be wiped clean with a soft cloth dampened with a mild detergent, e.g. soapy water. DO NOT use abrasive cleaning agents or polishes on this equipment.

Positioning light covers

The positioning light covers are made of clear plastic. Use a soft cloth dampened with a mild detergent, e.g. soapy water. NEVER use abrasive cleaning agents or polishes to clean the covers.

Surfaces that the patient touches

All surfaces and parts that the patient touches or comes into contact with must be disinfected after each patient. Use a disinfectant that is formulated specifically for disinfecting dental equipment and use the disinfectant in accordance with the instructions supplied with the disinfectant. All items and surfaces should be dried before next usage.

NOTE! *Wear gloves and other protective equipment during decontamination process.*

WARNING! *Do not use any disinfecting sprays since the vapor could ignite causing injury.*

Disinfecting techniques for both the unit and the room must comply with all laws and regulations that have jurisdiction of law within the jurisdiction on which the unit is.

Examples of cleaning agents that are allowed or prohibited when cleaning the unit

Allowed: Methanol (metyl alcohol), Soap, Isopropyl alcohol, distilled water.

Not allowed: Bentzene, Chlorine bentzene, Acetone, Acetic ether, agents containing phenol, paracetic acid,

peroxide and other oxygen-cleaving agents, sodium hypochlorite and iodine-cleaving agents.

6.4 Disposal

The device, its spare parts, its replacement parts and its accessories may include parts that are made of or include materials that are non-environmentally friendly or hazardous. These parts must be disposed of in accordance with all local, national and international regulations regarding the disposal of non-environmentally friendly or hazardous materials.

The locations of all parts can be found in the chapter 2.1, Main parts and controls.

Unit has at least the following parts that should be regarded as nonenvironmental friendly waste products:

- Tubehead (Pb)
- Collimator (Pb)
- All electronic circuits
- Sensor covers (EMC painted)

7 Technical data

7.1 Technical specifications

Manufacturer:	SOREDEX, PaloDEx Group Nahkelantie 160 (P.O. Box 20) FIN-04300 Tuusula, FINLAND
Quality system:	In accordance with ISO13485 and ISO9001 standard
Environmental management system:	In accordance with ISO14001 standard
Conformity to standards:	IEC 60601-1: 1988 and A1+A2 IEC 60601-1-1: 2000 IEC 60601-1-4: 1996 and A1 IEC 60601-2-7: 1998 IEC 60601-2-28: 1993 IEC 60601-2-32: 1994 IEC 60601-1-2: 2001 and A1 IEC 60601-1-3: 1994 UL 60601-1: 2003 CAN/CSA –C22.2 No. 601-1-M90 and S1+A2 standards This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture. CRANEX® 3D is in conformity with the provisions of Council Directive 93/42/EEC as amended by the Directive 2007/47/EC concerning medical devices. Performance Standards and European Union Directive 93/42/EEC (Medical Devices Directive).

Product name:	CRANEX® 3D
Model:	PP3-1
Product type:	Digital dental imaging system with panoramic, cephalometric and Cone Beam 3D imaging programs.

Unit data	
Protection against electric shock	Class I
Degree of protection	Type B applied with no conductive connection to the patient
Protection against the ingress of liquids	IP20
Disinfection methods	- mild soapy water (non-abrasive) - non-alcohol based disinfectant for the chin rest - disposable plastic covers for bite block, chin rest and chin support
For use	In environments where no flammable anaesthics nor flammable cleaning agents are present
Mode of operation	continuous operation/intermittent loading
Safety	IEC 60601-1
EMC Classification	Class B

Tube head assembly	
Tube head assembly type	THA 300
Tube type	Toshiba D-052SB, D-054SB-C Stationary anode
Tube voltage	57 - 90 kV
Max. tube current	16 mA
Max. electric output	1,44 kW
Target angle	5 degrees
Focal spot	0,5 x 0,5 mm (IEC 336/1982)
Nominal anode input	1750 W
Reference axis	In the middle of the panoramic sensor´s active area
Max. anode heat content	35 kJ
Max. X-ray tube assembly heat content	385 kJ
Max. continuous heat dissipation of the X-ray tube assembly	38 W

Tube head assembly	
Total filtration	>3,2 mm Al
Leakage Technical Factors	90 kV /4 mA

Electrical connections	
Nominal mains voltage	100-120 / 220-240 Vac (selectable)
Input power frequency	50 / 60 Hz
Nominal current	10A @ 230 VAC, 15A @ 110 VAC
Fuses	230 Vac: Littelfuse 326 (slow blow) 10A Cooper Bussman (time delay) MDA-10 110 Vac: Littelfuse 326 (slow blow) 15A Cooper Bussman (time delay) MDA-15
Power consumption	2.3 kVA @ 230 VAC, 1.65 kVA @ 110 VAC
Maximum impedance of main	0,2 Ω

Positioning laser lights	
Panoramic, TMJ & Maxillary Sinus Programs Cephalostat FH laser light 3D imaging programs	laser light (CLASS 1 LASER PRODUCT) max output 100µW Warning symbols are placed next to the laser lights and the label describing the laser light classification is placed inside the carriage side cabinet. USA / Canada models have different types of laser light stickers according to local requirements. Caution - use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
	IEC 60825-1:1993+A1:1997+A2:2001

High frequency DC generator	
Nominal power	1750 W nominal at 90 kV, 12 mA
Anode voltage	57 - 90 kV (+/- 5 kV)
Anode current	3,2 - 16 mA (+/- 1 mA)
Focal spot	0.5 mm
Minimum total filtration	3.2 mm Al
Supply frequency	75 - 150 kHz
Spine compensation	kV / mA compensated

User interface	
Program and technical factors selection, exposure control	Touch screen panel, removable exposure button with 10m cable
Patient positioning	Positioning panel, integrated
Connection cable (the unit - PC)	CAT6 Ethernet cable

Panoramic programs & Technical factors & magnification:		
Standard Adult Panoramic	57-90 kV/ 4-16 mA/ 16.4 s	30%
Child Panoramic	57-90 kV/ 4-16 mA/ 14.4 s	30%
TMJ PA	57-90 kV/ 4-16 mA/10.6 s	23%
TMJ Lateral	57-90 kV/ 4-16 mA/11.2 s	55%
Maxillary Sinus	57-90 kV/ 4-16 mA/12.5 s	30%
Bitewing (BW)	57-90 kV/ 4-16 mA/11.9 s	30%
Panoramic QC	57-90 kV/ 4-16 mA/16.4 s	30%

Exposure Control	Automatic Exposure Setting (AES) based on patient head size	

Cephalometric programs & Technical factors:	
Reduced width lateral view	60-90 kV / 4-16 mA / 6-14 s
Full width lateral	60-90 kV / 4-16 mA / 10-20 s
PA/AP, facial and oblique views	60-90 kV / 4-16 mA / 10-20 s
Carpus View (Not in USA and Canada and Canada)	60-90 kV / 4-16 mA / 10-20 s
Exposure Control	Automatic Exposure Setting (AES) based on patient head size
Magnification factor	1.14 (14%)

3D imaging programs:	
XS FOV dimensions	61 x 41 mm (HxD)
Midi FOV (optional) dimensions	61 x 78 mm (HxD)
Technical factors	
XS FOV standard resolution	90 kV / 6.3 - 12.5 mA / 2.3 s
Midi FOV (optional) standard resolution	90 kV / 6.3 - 12.5 mA / 4.9 s
XS FOV High resolution	90 kV / 4 - 12.5 mA / 6.1 s
Midi FOV (optional) High resolution	90 kV / 4 - 10 mA / 12.6 s
XS FOV scout	90 kV / 4 - 12.5 mA / 0.02 s
Midi FOV (optional) scout	90 kV / 4 - 12.5 mA / 0.04 s

Image storing and retrieving:	
File formats	PNG (16-bit), JPG (12-bit)
File compression	PNG (lossless), JPG (100%-60% quality)
Typical panoramic file size	About 2-4 MB (PNG 16 bits)
Typical cephalometric file size	3-5 MB (PNG 16 bits)
Typical 3D file size	150-250 MB (DICOM)

Image storing and retrieving:	
Patient database	Standalone workstation Server on local area network (LAN)

Panoramic patient positioning	
Operation	Left Motorised carriage movement
Positioning aids	Chin rest, bite block, 3-point headrest Hinged mirror, 3 positioning laser lights, Y-layer step less adjustment

Cephalostat patient positioning	
Operation	Arm mounts on left or right side of the unit Interlocked pan/ceph sensor Motorised carriage buttons at cephalostat head assembly.
Positioning aids	Ear holders, Nasion support with vertical mm scale, Frankfurt horizontal plane laser light, Contact plate (Carpus view).

3D imaging patient positioning	
Operation	Left Motorised carriage movement
Positioning aids	Chin rest, chin support, chin cup 3-point headrest, hinged mirror, 3 positioning laser lights

Cephalostat scanning	
Scanning method	Horizontal scan, synchronized sensor and secondary slot motion
Scanning time	10 - 20 s.

Panoramic image receptor	
Sensor unit	Pan sensor or interchangeable Ceph sensor
Technology	CMOS

Panoramic image receptor	
Image pixel size	100 x 100 μm
Active area height	5.8 inches / 148 mm / 1480 pixels
Resolution	Pan: 5 LP/mm

Cephalometric image receptor	
Sensor unit	interchangeable Ceph sensor
Technology	CMOS
Image pixel size	100 x 100 μm
Active area height	223,2 mm / 2232 pixels
Image field width in lateral view	10.2 inches / 260 mm, maximum 6.7 inches / 170 mm, minimum
Image field width in PA view	7.9 inches / 200 mm
Resolution	4 LP/mm

3D image receptor	
Sensor unit	3D sensor
Technology	CMOS Flat Panel
Image pixel size	200 μm
Active sensor surface (H x W)	100 x 68 mm

Unit physical measures:	
Source-image distance (SID)	500 mm (Panoramic) 570 mm (3D)
Installation	Standard wall mount with ±45° angled joint. Optional base for free standing unit (unit height is increased 25 mm).
Height x Width x Depth (inches/mm)	2414x965x1126mm (standard column) 94.9 x 38 x 44.3 inches -Max.
Weight	200 kg / 440 lbs. (Panoramic)

Unit ceph physical measures:	
Source-image distance (SID)	68.7 inches / 1745 mm
Source-object distance (SOD)	60 inches / 1520 mm
Installation	Standard wall mount with 45° angled joint. Optional base for free standing unit (unit height is increased 25 mm)
Height x Width x Depth (inches/mm)	2414 x 1872 x 1126 mm 94.9 x 73.7 x 44.3 inches
Weight	250 kg / 551 lbs. (Cephalometric)

Ambient temperatures:	
Transportation and Storage	-10°…+60°C
Operation Temperature	+10°...+35°C, RH max. 85%

Minimum PC requirements for Modality workstation (3D acquisition workstation):	
Processor	2.5 GHz dual core, or better
Memory	3 Gigabytes RAM, or more
Hard disk	500 GB, or more
Expansion slot	PCI-Express bus for supplied GPU, full length
Power supply	500 watt minimum
Network	Gigabit Ethernet 1000Base-T
Operating system	Windows 7 or Windows Vista (32 or 64-bit)
Display	20" LCD display, 1600 x 1200 or 22" LCD widescreen display, 1680 x 1050, or better
Standard	The PC must meet the IEC 60950 standard (minimum requirements)
Graphics card	GTX 460 Nvidia Quadro GPU, FX 3800 Nvidia Quadro, NVidia Quadro 4000 (NVidia driver version 259.57)
PCI board connection	Full-length PCIe x16 slot (for GPU board)
USB	USB ports (for HASP Dongle keys) • 1 for reconstruction system (Dongle supplied with Mercury GPU Kit) • 1 for OnDemand3D (Dongle supplied with CD Kit)
Color monitor size	20” 2MP LCD display, 1600 x 1200 (19” 1.3MP LCD 1280 x 1024, minimum)
Mouse	Mouse with scroll wheel

NOTE! *This is an abbreviated list of requirements. Please refer to the software installation manual or contact your local dealer for detailed installation requirements.*

Minimum PC requirements for Viewing workstation for 2D/3D images:	
Processor	2.0 GHz dual core, or better
Memory	2 Gigabytes RAM, or more
Graphics	NVIDIA GeForce 6600 or ATI Radeon X700 or better; 256MB or more memory (integrated graphics are not supported)
Hard disk	3 GB free space, or more
Network	Gigabit Ethernet 1000Base-T (recommended) or Fast Ethernet 100Base-TX
Operating system	Windows 7 or Windows Vista (32 or 64-bit)
Display	19" LCD display, 1280 x 1024, or better

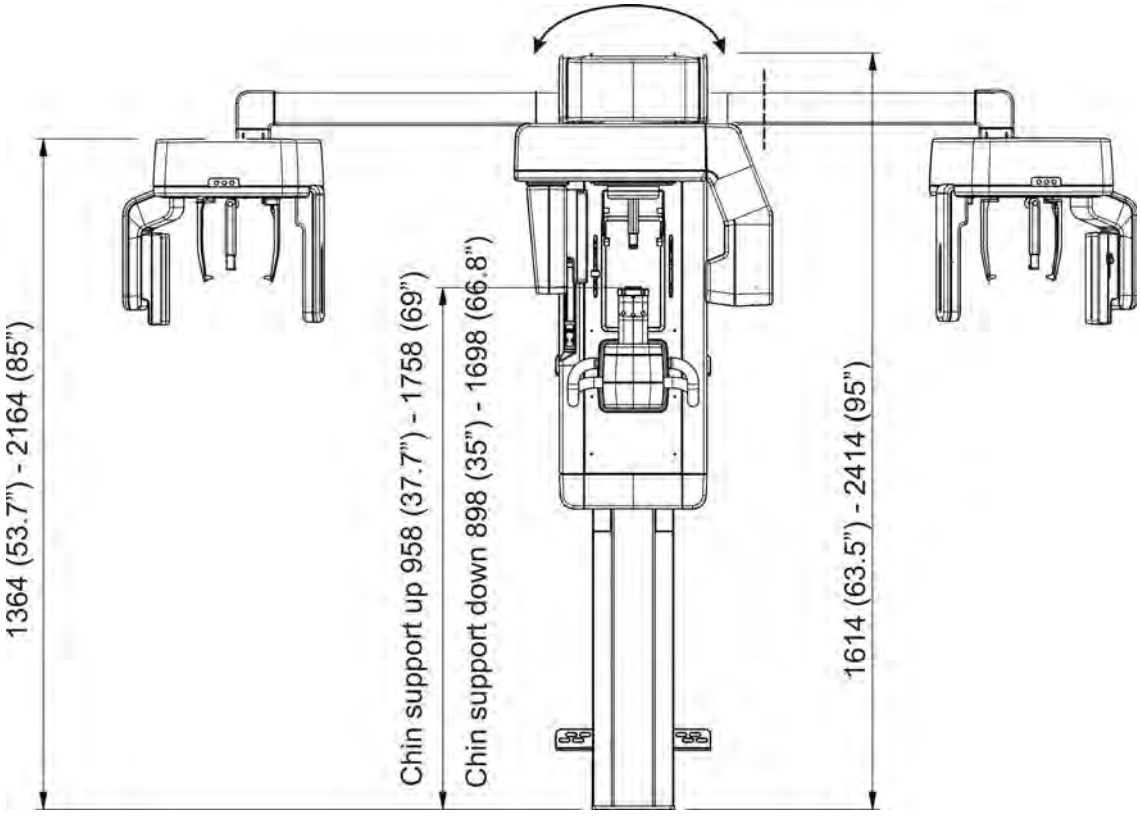
System requirements and connections

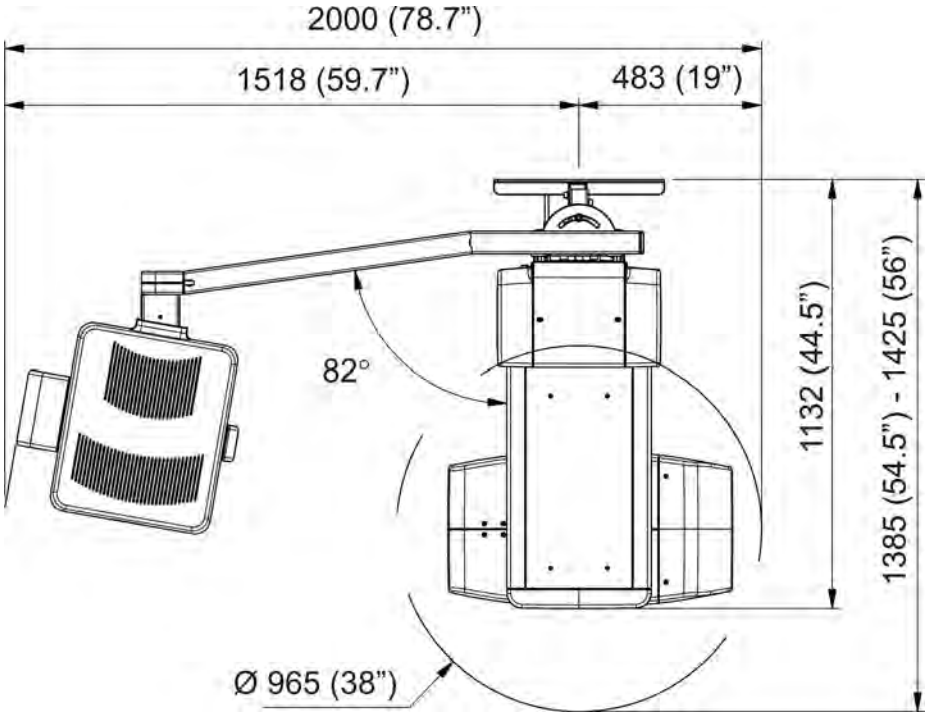
- The PC and any other external device(s) connected to the system must meet the IEC 60950 standard (minimum requirements). Devices that do not meet the IEC 60950 standard must not be connected to the system as they may pose a threat to operational safety.
- The PC and any other external devices must be connected in accordance with IEC 60601-1-1.
- The x-ray unit must be connected to it’s own separate power supply. The PC and any other external devices must NOT be connected to the same power supply as the x-ray unit.
- Position the PC and any other external device at least 1.5 m (60”) from the xray unit so that the patient cannot touch the PC or any other external device while being x-rayed.
- The PC and any other external devices shall not be connected to an extension cable.
- Multiple extension cables shall not be used.
- Do not position the PC where it could be splashed with liquids.
- Clean the PC in accordance with the manufacturer’s instructions.

Ceph ready option (Ordered separately)	
Options	**Description**
Interchangeable Ceph sensor with the pan unit	Unit has the same sensor as ceph unit. Cost saving with future digital ceph upgrade.

Field upgrades for the unit	
Upgrade	Description
Digital Cephalostat Kit	Add digital ceph imaging to the digital pan unit

7.2 Unit dimensions





7.3 Symbols that appear in the unit

Radiation warning

Dangerous voltage

On or enabled

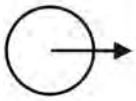
Off or disabled

Connector for remote control

Exposure switch

Connector for Ethernet RJ45

Connector for exposure switch


Connector for external exposure light

Attention, consult accompanying documents

Ground (Functional)

Protective ground

CLASS 1 LASER PRODUCT

EN 60 825-1/A2:2001

Laser class label
(Patient positioning lights)

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Type B equipment

CE
0537

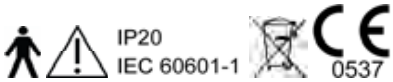
CE (0537) symbol
MDD 93/42/EEC

ETL CLASSIFIED
CONFORMS TO UL STD 60601-1.
CERTIFIED TO CSA
STD C22.2 NO 601.1.

7.4 Labels on the unit

The main label of the unit is located on the vertical carriage next to the on/off power switch. The unit is class I, type B and with IP20 protection.

Type: PP3 - 1
Ser. No:
Manufactured:
10 A 220 - 240 V~ 50 / 60 Hz (1A continuous)
15 A 100 / 120 V~ 50 / 60 Hz (1A continuous)



This product complies with DHHS 21 CFR Chapter I, Subchapter J at the date of manufacture.
Rx only.

Warning:

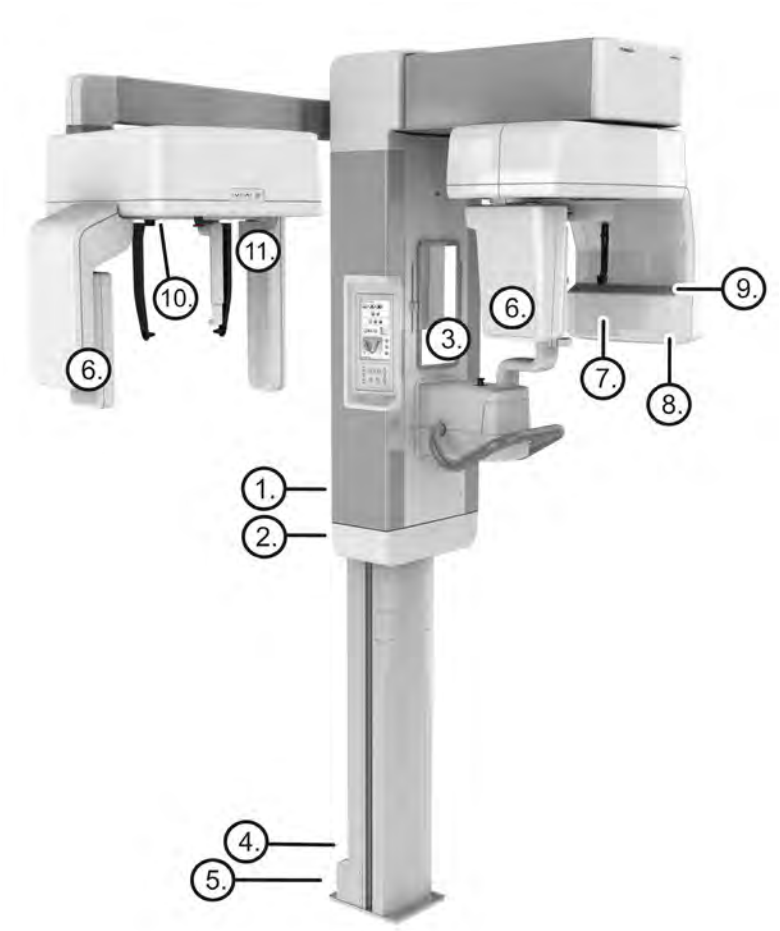
This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

ETL CLASSIFIED
CONFORMS TO UL STD 60601-1.
CERTIFIED TO CSA
STD C22.2 NO 601.1.

Manufactured by Soredex
Nahkelantie 160
FI-04300 TUUSULA, Finland

D502470

7.5 Unit identification labels



1. Main label
2. 10A & 15A Fuse label (next to the fuse holders)
3. Laser class 1 warning label IEC 60825-1:2007
4. Ethernet and remote exposure button label
5. Warning label for line voltage connection (on the power cord)
6. Sensors (on the sensor)
7. (Primary) collimator label (on the collimator and on the tubehead cover)
8. Tubehead label (on the tubehead and on the tubehead cover)
9. Warning label for deadly voltages (inside the tubehead cover)
10. Cephalostat (outside on the cover)
11. Secondary collimator (on the secondary collimator and on the collimator cover)

7.6 Electromagnetic Compatibility (EMC) tables

NOTE! *Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information.*

CRANEX® 3D is suitable for use in the specified electromagnetic environment. The purchaser or user of CRANEX® 3D should assure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment
Radio-Frequency Emissions CISPR11	Group 1	CRANEX® 3D uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Radio-Frequency Emissions CISPR11	Class B	CRANEX® 3D is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	IEC 61000-3-2 Class A	CRANEX® 3D is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	CRANEX® 3D is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 7.1 Electromagnetic emissions IEC 60601-1-2 Ed2

CRANEX® 3D is suitable for use in the specified electromagnetic environment. The purchaser or user of CRANEX® 3D should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	Floors are wood, concrete, or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality is that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality is that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T)	< 5 % U_T (> 95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T)	Mains power quality is that of a typical commercial and/or hospital environment. If the user of CRANEX® 3D requires continued operation during power mains interruptions, it is recommended that CRANEX® 3D be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Table 7.2 Electromagnetic immunity IEC 60601-1-2 Ed2

CRANEX® 3D is suitable for use in the specified electromagnetic environment. The purchaser or user of CRANEX® 3D should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF IEC 61000-4-6	3 V150 kHz to80 MHz	[V_1] 3 V	Portable and mobile RF communications equipment are used no closer to any part of CRANEX® 3D, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended Separation Distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RFIEC 61000-4-3	3 V/m80 MHz to2,5 GHz	[E_1] 3 V/m	$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,* are less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol:

*Field strengths from fixed transmitters, such as base stations for cellular telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be estimated accurately. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be performed. If the measured field strength exceeds the RF compliance level above, observe CRANEX® 3D to verify normal operation in each use location. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating CRANEX® 3D.

**Over the frequency range 150 kHz to 80 MHz, field strengths are less than [V_1] V/m.

The Recommended Separation Distances are listed in the next table.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 7.3 RF immunity of non-life-support equipment or system IEC 60601-1-2

NOTE! *RF communications equipment can effect medical electrical equipment.*

NOTE! *This equipment generates, uses and can radiate radio frequency energy. If not installed and used in accordance with this manual, it may cause harmful interference to radio communications. Portable and mobile RF communications equipment can also affect the performance of CRANEX® 3D.*

Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2			
Frequency of Transmitter	150KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
Equation	$d = [\frac{3,5}{V_1}]\sqrt{P}$	$d = [\frac{3,5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$
Rated Maximum Output Power of Transmitter (watts)	Separation Distance (meters)	Separation Distance (meters)	Separation Distance (meters)
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,34
10	3,69	3,69	7,38
100	11,67	11,67	23,34

Fig 7.1. Table 4

USE LIMITATION:

External components

The use of accessories, transducers, and cables other than those specified may result in degraded ELECTROMAGNETIC COMPATIBILITY of the EQUIPMENT and/or SYSTEM

INSTALLATIONS REQUIREMENTS & ENVIRONMENT CONTROL :

In order to minimize interference risks, the following requirements shall apply.

Cables shielding & grounding

All interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference.

Electrostatic discharges environment & recommendations

In order to reduce electrostatic discharge interference, a charge dissipative floor should be installed to prevent charge accumulation.

- The dissipative floor material must be connected to the system reference ground, if applicable.
- Relative humidity must be maintained above 30 percent.

Stacked components & equipment

The unit should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the unit should be observed to verify normal operation in the configuration in which it will be used.

Interference may occur in the vicinity of equipment marked with the following symbol:

No portable or mobile RF com*munications equipment may be used closer to any part of the unit, including cables, than the recommended separation di*stance calculated from the equation appropriate to the frequency of the transmitter.
See Table 4.

7.7 X-ray tube assemblies

Duty cycle 1:8

Rectification type: Constant potential x-ray generator

Generator rating: Generator nominal power 1750W

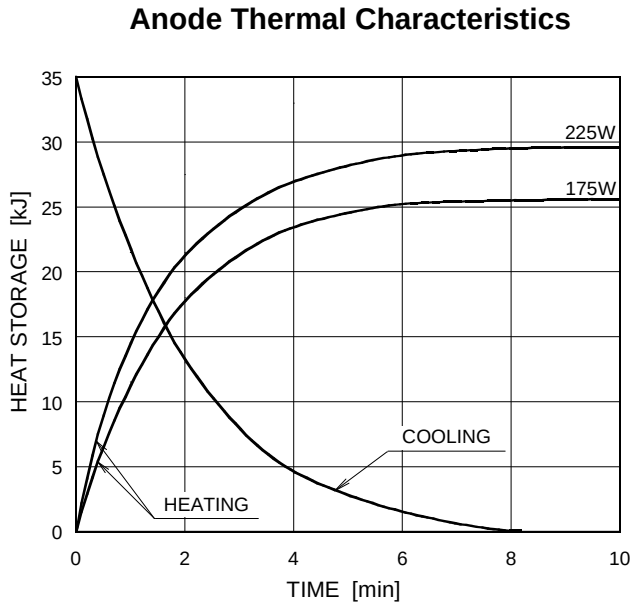


Fig 7.2.

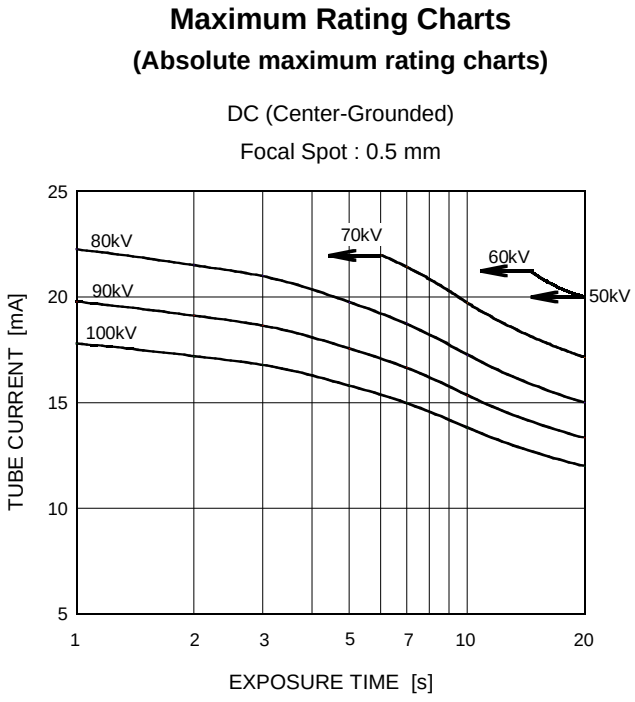


Fig 7.3.

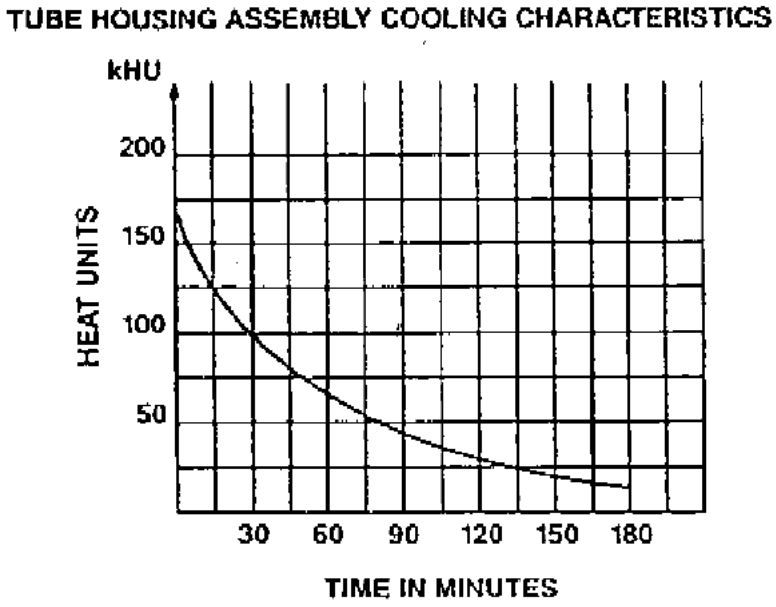

TUBE HOUSING ASSEMBLY COOLING CHARACTERISTICS
kHU
200
150
100
50
HEAT UNITS
30
60
90
120
150
180
TIME IN MINUTES

Fig 7.4.